

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI**

State of Missouri,

Plaintiff,

v.

United States Department of Health and
Human Services; and Xavier Becerra, in
his official capacity as Secretary of the
United States Department of Health and
Human Services,

Defendants.

Civil Action No. 4:25-cv-00077-JAR

**APPENDIX IN SUPPORT OF
INTERVENOR-DEFENDANTS' MOTION TO INTERVENE**

<u>Ex.</u>	<u>Exhibit Description</u>	<u>Bates Number</u>
A	Declaration of Dr. Christine Petrin	Appx. 005
B	Declaration of Dr. Beth Oller	Appx. 011
C	Declaration of Edward Johnson	Appx. 016
D	Declaration of Janel Heinrich	Appx. 024
E	Health Insurance Portability and Accountability Act, Pub. L. 104-191, 110 Stat. 1936	Appx. 032
F	Administrative Procedure Act, 5 U.S.C. § 706(2)	Appx. 157
G	HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 89 Fed. Reg. 32976 (Apr. 26, 2024)	Appx. 159
H	Ohio Const. art. XVIII	Appx. 318
I	Wis. Stat. Ch. 66.0201–03	Appx. 333

J	45 C.F.R. § 160.103	Appx. 341
K	42 U.S.C. § 1320d-5	Appx. 351
L	42 U.S.C. § 1320d-6(b)	Appx. 357
M	Am. Med. Ass'n, Opinion 1.1.1: <i>Patient-Physician Relationships</i> , Code of Medical Ethics (Aug. 2022), https://code-medical-ethics.ama-assn.org/sites/amacoedb/files/2022-08/1.1.1.pdf	Appx. 359
N	Tyler Arnold, <i>Trump's HHS nominee Robert F. Kennedy Jr. reassures pro-life senators with policy plans</i> , Catholic News Agency (Dec. 18, 2024), https://www.catholicnewsagency.com/news/261111/trump-hhs-nominee-robert-kennedy-jr-reassures-pro-life-senators	Appx. 366
O	Eric Cortellessa, <i>How Far Would Trump Go</i> , TIME (Apr. 30, 2024), https://time.com/magazine/us/6979410/may-27th-2024-vol-203-no-17-u-s/	Appx. 372
P	Excerpt, The Heritage Foundation, <i>Mandate for Leadership: The Conservative Promise</i> 497 (2023), https://static.project2025.org/2025_MandateForLeadership_FULLL.pdf	Appx. 383
Q	Jessica Valenti, <i>Breaking: Trump is Scrubbing HIPAA Info off HHS Website</i> , Abortion, Every Day (Feb. 3, 2025), https://jessica.substack.com/p/hipaa-hss-deleted-trump?utm_source=post-email-title&publication_id=11153&post_id=156391191&utm_campaign=email-post-title&isFreemail=true&r=45umgj&triedRedirect=true&utm_medium=email	Appx. 386
R	Exec. Order No. 14076, 87 Fed. Reg. 42053 (2022)	Appx. 390

Date: February 10, 2025

Respectfully submitted,

/s/ Sharon B. Rosenberg

Sharon B. Rosenberg
THOMPSON COBURN LLP
One US Bank Plaza
St. Louis, Missouri 63101
(314) 552-6173
srosenberg@thompsoncoburn.com

Counsel to Intervenor-Defendants

-and-

Shannon Rose Selden – *Pro Hac Vice Pending*
Zachary H. Saltzman – *Pro Hac Vice Pending*
Adam Aukland-Peck – *Pro Hac Vice Pending*
DEBEVOISE & PLIMPTON LLP
66 Hudson Boulevard
New York, New York 10001
(212) 909-6000 (phone)
(212) 909-6836 (fax)
srselden@debevoise.com
zhsaltzm@debevoise.com
aauklandpeck@debevoise.com

Counsel to Intervenor-Defendants

-and-

Anna A. Moody – *Pro Hac Vice Pending*
Gabriel A. Kohan – *Pro Hac Vice Pending*
Suzanne Zakaria – *Pro Hac Vice Pending*
DEBEVOISE & PLIMPTON LLP
801 Pennsylvania Avenue NW
Washington, DC 20004
(202) 383-8000 (phone)
(202) 383-8118 (fax)
amoody@debevoise.com
gakohan@debevoise.com
szakaria@debevoise.com

Counsel to Intervenor-Defendants

Carrie Y. Flaxman – *Pro Hac Vice Pending*
Madeline H. Gitomer – *Pro Hac Vice Pending*
Emma R. Leibowitz – *Pro Hac Vice Pending*
DEMOCRACY FORWARD
P.O. Box 34553
Washington, DC 20043
(202) 448-9090 (phone)
cflaxman@democracyforward.org
mgitomer@democracyforward.org
eleibowitz@democracyforward.org

Counsel to Intervenor-Defendants

-and-

Aisha Rich – *Pro Hac Vice Pending*
Shannon Eddy – *Pro Hac Vice Pending*
PUBLIC RIGHTS PROJECT
490 43rd Street, Unit #115
Oakland, California 94609
(510) 214-6960 (phone)
aisha@publicrightsproject.org
shannon@publicrightsproject.org

*Counsel to City of Columbus and City of
Masion*

CERTIFICATE OF SERVICE

I hereby certify that on February 10, 2025, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

/s/ Sharon B. Rosenberg
Sharon B. Rosenberg

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
ST. LOUIS DIVISION**

State of Missouri,

Plaintiff,

v.

United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; Office for Civil Rights of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services,

Defendants.

Civil Action No. No. 4:25-cv-00077

DECLARATION OF DR. CHRISTINE PETRIN

I, Christine Petrin, hereby declare under penalty of perjury as prescribed in 28 U.S.C. § 1746 that the following is true and correct:

1. My name is Christine Petrin. I am over eighteen years old, of sound mind, and fully competent to make this declaration. I also have personal knowledge of the factual statements contained herein. I provide this declaration in support of the motion to intervene.

2. I am a primary care physician at Settlement Health and a Clinical Instructor of Internal Medicine & Pediatrics at Mount Sinai Hospital, both in New York, New York. My driving mission as a physician is to improve the lives of children, adults, and their communities.

3. I received my medical degree from Tulane University School of Medicine in New Orleans, Louisiana. I did a dual medical residency in internal medicine and pediatrics at MedStar Georgetown University Hospital in Washington, D.C., where I was the Chief Resident.

4. Since February 2024, I have served as the President and Chair of the Board of Doctors for America (DFA). I previously served as both Vice Chair and Secretary of the Board and have been a member of DFA since 2018.

DFA and its Members

5. DFA is a nonprofit organization organized under Section 501(c)(3) of the Internal Revenue Code. Founded in 2009, DFA works on behalf of its members to improve the health of patients, communities, and the nation. One of our guiding principles is that clinicians must take a leading role in improving health care and ending health disparities, and we provide our members with the tools to do so. We advocate on our members' behalf for policies that allow them to provide equitable and accessible care to patients.

6. DFA is comprised of more than 27,000 medical professionals, medical students, and health care advocates who live in all fifty states and the District of Columbia, work in various practice settings, including in hospitals, academia, and in private practice, and represent all areas of specialization.

7. DFA members have access to various DFA resources, including continuing medical education and other training, events, and advocacy tools. DFA also drafts resources to keep our members up to date on the latest developments in health policy.

8. DFA members, including myself, serve in various capacities in the organization, including on the Board of Directors, and drive our organizational focus areas: health justice and equity; access to affordable care; and community health and prevention. In each of these

buckets, DFA provides education and training to its members and engages in advocacy at the state and federal levels. Through these efforts, we work to improve outcomes for the patients we serve.

9. DFA's health justice and equity work involves efforts to reduce health disparities among marginalized communities and populations. As part of that work, DFA works to protect access to reproductive health care services for all patients. DFA is also one of two founding organizational members of the Reproductive Health Coalition, a group of 120 medical-professional associations and allied organizations that collectively represent over 150 million voices in medicine, health care, and other groups.

DFA Members and HIPAA

10. Many DFA members are "health care providers" and "covered entities" subject to the Health Insurance Portability and Accountability Act ("HIPAA") and its regulations, including the 2024 HIPAA Reproductive Health Rule ("2024 Rule").

11. As professionals who are required to comply with HIPAA, these DFA members are impacted by any changes to the law and its regulations, which covered entities have relied on for decades. These DFA members are required to have in place and adhere to HIPAA policies and procedures (and are subject to the internal HIPAA policies of the entities they work for), receive at least annual training on what HIPAA requires, and offer patients information about their rights under HIPAA.

12. Day-to-day, our clinician members rely on HIPAA to guide when and how patient information may and may not be used or disclosed. The presence of national baseline requirements regarding the use and disclosure of patient information helps DFA members stay confident that they are appropriately safeguarding patient information and adhering to their

ethical obligations to do so. In response to administrative subpoenas and investigative demands, for example, medical practices can rely on the three preconditions under HIPAA that must be met prior to disclosing medical information in order to appropriately protect patient information.

13. DFA and its members believe that the privacy protections that HIPAA affords are integral to maintaining trust between clinicians and their patients—a key but fragile component of providing quality care. We believe that privacy is necessary for the efficient and effective delivery of health care because trust and confidentiality are at the very core of the provider-patient relationship, and those relationships and the health care system as a whole, are built upon the willingness of individuals to share the most intimate details of their lives with their health care providers. HIPAA is a key tool for assuring patients that their medical information will be protected, which increases patient trust, encourages patients to be open with their clinicians, and, in turn, allows us to give them the best possible care.

14. If HIPAA and its underlying rules were in any way threatened, it would inject significant confusion into our jobs and impair the provider-patient relationship necessary to deliver adequate health care. Without a federal standard to govern the use and disclosure of medical information, I do not know how clinicians could reliably share information without becoming expert in numerous state laws. That would be time-consuming, costly, and unworkable, including because medical professionals would need to completely rebuild their privacy compliance programs, of which HIPAA has been the foundation for decades, thereby incurring unexpected and potentially significant compliance costs.

15. The 2024 Rule specifically put in place important restrictions on using and sharing patient information about their reproductive health care, providing DFA's members with clarity on how they can use and disclose this particularly sensitive patient information. Many

DFA members provide reproductive health services on a regular basis, while others provide such care as necessary. Members who do not provide reproductive health care may obtain sensitive information about their patients' reproductive health care in the course of providing treatment, and record that information in the medical record.

16. DFA members have been increasingly concerned that patient medical information may be sought and used improperly for non-health care purposes following the *Dobbs* decision, including from investigations into doctors providing legal and necessary health care and patients obtaining it. The 2024 Rule has helped mitigate these risks to providers like many of DFA members and strengthened the doctor-patient relationship because it allows them to explain to patients how their reproductive health information is protected from misuse. If the 2024 Rule is vacated, it is likely that some patients seeking reproductive health care would forgo such care, and that patients will withhold critical reproductive health information relevant for proper medical treatment from their clinicians.

17. Without the protections of the 2024 Rule, providers would have less ability to protect the sensitive medical information they receive from misuse, and our members would face increased challenges in their ethical and professional duties to provide effective care to their patients. Patients would not be willing to share relevant medical information with their providers for fear it may not be protected. Other patients may forgo care altogether. The provider-patient relationship, based on trust, would be fractured. And, fundamentally, that would negatively affect patient care. In turn, DFA would need to expend significant resources to account for this sea change in patient protection privacy—updating its materials and reorienting its advocacy work.

Executed on February 10, 2025

A handwritten signature in cursive script, appearing to read "Christine Petrin", written in black ink on a white background.

Dr. Christine Petrin

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
SOUTHEASTERN DIVISION**

State of Missouri

Plaintiff,

v.

United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; Office for Civil Rights of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services,

Defendants.

Civil Action No. 4:25-cv-00077

DECLARATION OF DR. BETH OLLER

I, Beth Oller, hereby declare under penalty of perjury as prescribed in 28 U.S.C. § 1746 that the following is true and correct:

1. My name is Beth Oller. I am over eighteen years old, of sound mind, and fully competent to make this declaration. I also have personal knowledge of the factual statements contained herein. I submit this declaration in support of Doctors for America's ("DFA") motion to intervene.

2. I have a Bachelor of Science in Nursing from the University of Kansas and received my medical degree from the University of Kansas School of Medicine. I did my residency at the Wesley Family Medicine Residency Program in Wichita, Kansas. Since I

completed my residency more than fifteen years ago, I have practiced medicine in Rooks County, Kansas—a rural part of the state with approximately 5,000 residents.

3. I am currently a primary care provider at the Rooks County Health Center. I treat hundreds of patients. For more than a decade before that, I ran a small private practice in Rooks County.

4. I have been a member of DFA since 2022. I became a member of DFA when I became increasingly concerned that the Supreme Court would overturn the constitutional protections related to abortion.

5. Since then, I have relied on DFA's resources to educate myself and advocate for laws and policies that increase access to reproductive and other health care. For example, Kansas is one of only a few states that has not expanded Medicaid. I have used DFA's resources to understand how I can directly support efforts to change that. I have also attended several DFA webinars and use DFA's communications to stay up to date on the laws and policies relevant to my practice.

6. As a family medicine physician, I care for patients of all ages. My daily practice involves everything from conducting yearly check-ups to treating common illnesses such as colds and the flu and screening and treating for conditions such as high blood pressure or diabetes.

7. I also provide a range of reproductive healthcare. For example, I provide birth control and talk with my patients about family planning, refer pregnant patients to nearby obstetricians and may provide them with interim care, help my patients manage miscarriages, and treat moms (and their babies) post-birth. For more than a decade of my career, I also delivered babies. My patients often provide me with their medical histories, which can include

sensitive information my patients intend to keep otherwise confidential, such as whether they have had an abortion.

8. As a physician, I am subject to and must comply with the Health Insurance Portability and Accountability Act (“HIPAA”) and its privacy rules.

9. I use HIPAA and its privacy rules, including the 2024 HIPAA Reproductive Health Rule (“2024 Rule”), as tools to improve my work. My ethical and professional duties are to provide the care my patients need. An important part of satisfying those duties is making sure my patients know that they can trust me and that my clinic is safe for them.

10. HIPAA and its privacy rules provide a backstop when I need to explain to my patients how their information may or may not be shared, including with family members who—especially in the small community in which I practice—may ask for it. It’s a foundational protection that my patients know and understand, and it’s crucial to maintaining the confidentiality of my patients’ records and, in turn, their trust.

11. This trust is essential to my practice. If patients don’t believe that I’ll keep their information private, they won’t come to my office or they won’t tell me everything I need to know to provide them with optimal care. For example, if a patient who has miscarried before doesn’t feel safe sharing that fact with me, I can’t give her correct advice on how much time she should wait before trying to get pregnant again.

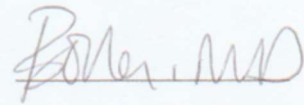
12. In the context of providing reproductive health, this trust has been increasingly threatened since the *Dobbs* decision. The 2024 Rule gives my patients an extra assurance that their particularly sensitive information will be kept private. Without it, I would be concerned that my patients considering abortion care, for example, would no longer come to me to learn about their options.

13. HIPAA and its privacy rules also help me work effectively with the other providers my patients see. To provide comprehensive, quality care to my patients—and for my patients’ other providers to do the same—we must share patient information. Where I work in rural Kansas, that might even require me to share and receive patient information across state lines. HIPAA and its privacy rules allow all providers to operate under a common baseline of patient privacy protections.

14. If HIPAA was struck down, it would sow chaos in the medical profession and negatively impact my patients. HIPAA and its privacy rules are the building blocks on which other patient privacy laws and policies are crafted. If the law or the 2024 Rule were thrown out, health care providers would need to update their policies based on the patchwork of state laws that would emerge (many of which had previously relied on HIPAA and its privacy rules) and their own assessments of the proper balance between patient privacy and other concerns. And different practices might reach different conclusions, making it hard to share information among providers. That would cause complications in my own practice when, for example, I had to send critical health information from a patient’s neurologist in Nebraska or get information from a patient’s OB-GYN three hours away in Wichita.

15. Undermining HIPAA and its privacy rules, including the 2024 Rule, would be detrimental to patient health and public health generally. HIPAA is the foundation of patient privacy, and my patients understand that their information is protected by federal law. If HIPAA or the 2024 Rule were to be overturned, it would deeply harm the level of trust my patients have in me, threatening my relationships with them and inhibiting my ability to provide care for them.

Executed on February 7, 2025

A handwritten signature in dark ink, appearing to read "Beth Oller", written over a horizontal line.

Dr. Beth Oller

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI**

STATE OF MISSOURI,

Plaintiff,

v.

No. 4:25-cv-00077

**U.S. DEPARTMENT OF HEALTH &
HUMAN SERVICES, et al.,**

Defendants.

DECLARATION OF EDWARD JOHNSON

I, Edward Johnson, hereby declare under penalty of perjury as prescribed in 28 U.S.C. § 1746 that the following is true and correct:

1. My name is Edward Johnson. I am over eighteen years old, of sound mind, and fully competent to make this declaration. I also have personal knowledge of the factual statements contained herein. I provide this declaration in support of the motion for intervention.

2. I am currently the Assistant Public Health Commissioner for External Affairs and Acting Chief Health Equity Officer for the Columbus Department of Public Health ("Columbus Public Health"). I have served as an Assistant Public Health Commissioner for close to three years.

3. Prior to my role as Assistant Public Health Commissioner, I served Columbus Public Health as the Director of Public Health Policy for over four years.

4. As Columbus Public Health's Assistant Public Health Commissioner for External Affairs and Acting Chief Health Equity Officer, I assist the Health Commissioner with representing the needs and concerns of Columbus' residents to protect their health and improve their lives.

Columbus Public Health

5. The City of Columbus, Ohio, is a municipal corporation organized under Ohio law. Columbus has all the powers of local self-government and home rule under the constitution and laws of the state of Ohio, which are exercised in the manner prescribed by the Charter of the City of Columbus.

6. Columbus, located in Franklin County, is the capital of Ohio. It is the largest city in the state and the fourteenth largest city in the United States, with a population of over 905,000, according to 2020 Census estimates.

7. Columbus provides a wide range of services on behalf of its residents, including health services for families and children, public health, public assistance, and emergency medical care.

8. Columbus's public health department, Columbus Public Health, is a city agency charged with protecting the health and improving the lives of all the residents of Columbus, Ohio. Columbus Public Health works to ensure that the Columbus community is protected from disease and other public health threats and that Columbus residents are empowered to live healthier lives.

9. Columbus Public Health employs close to 600 employees who operate more than 90 different public health programs and provide critical services to residents. These programs and services include testing and treatment for sexually transmitted infections, including human

immunodeficiency virus (“HIV”), women’s health and wellness services, postpartum and newborn home visiting, immunizations, dental services, and medication assisted treatment for substance use, among others.

10. Columbus Public Health operates 9 outpatient clinics where doctors and nurse practitioners treat approximately 10,000 patients each year. Many of Columbus Public Health’s employees work in these clinics, which include the Women’s Health and Wellness Center and the Sexual Health and Wellness Center.

11. All Columbus Public Health clinics accept and bill both private and public insurers for patients who have health insurance. Clinic staff members assist uninsured patients with enrolling in Medicaid. Clinics also provide free services for uninsured and underinsured patients.

12. Columbus Public Health’s Women’s Health and Wellness Center provides confidential reproductive health care for women, their partners and teens; testing, treatment and prevention education for sexually transmitted infections; well woman annual exams and cancer screenings; contraceptive services, including long-acting methods (implant and IUD); reproductive life planning; pregnancy testing; and other medical services.

13. A critical part of the Women’s Health and Wellness Center’s work relates to the provision of reproductive health care services. These services enable every Columbus resident to make and carry out their own reproductive decisions, consistent with Article I, Section 22 of the Ohio Constitution.

14. Columbus’s Sexual Health and Wellness Clinic offers testing and treatment for sexually transmitted infections, medication to prevent HIV infections, preconception health and

pregnancy testing, emergency contraception, and wellness services such as diabetes and cholesterol screenings, among others.

Columbus Public Health and HIPAA Privacy Protections

15. Columbus Public Health's clinics and many of its employees are "health care providers," and the clinics are a "covered entity" subject to the Health Insurance Portability and Accountability Act ("HIPAA") and its regulations, including the 2024 HIPAA Reproductive Health Rule ("2024 Rule"). As a covered entity, Columbus Public Health is impacted by any changes to HIPAA and its regulations. Columbus Public Health clinics are required to have in place and adhere to HIPAA policies and procedures, provide at least annual training on what HIPAA requires, and offer patients information about their rights under HIPAA.

16. Columbus Public Health takes its HIPAA obligations seriously and employs a dedicated Health Information Manager and HIPAA Privacy and Security Officer. The HIPAA Privacy and Security Officer has developed and keeps up to date Columbus Public Health's HIPAA compliance program and ensures that HIPAA policies are enforced and that patient information remains secure.

17. Columbus Public Health has developed annual HIPAA training materials and updates them so that they reflect any changes to HIPAA rules and regulations. Our HIPAA Privacy and Security Officer also provides updates on HIPAA compliance to all employees through a periodic department-wide newsletter.

18. HIPAA and its relevant regulations, including the 2024 HIPAA Reproductive Health Rule ("2024 Rule"), support the work of Columbus Public Health. National baseline requirements regarding the use and disclosure of patient information allow Columbus Public

Health clinicians to be confident that they are appropriately protecting their patients' medical information.

19. The privacy protections that HIPAA affords are critical to establishing and maintaining trust between our doctors and nurses and their patients. The delivery of quality health care depends on individuals being willing to share the most intimate details of their lives with their health care providers. HIPAA is a key tool providers can use to assure patients that their medical information will be kept safe. This increases patient trust, encourages patients to be open, and, in turn, allows clinicians to give them the best possible care.

20. This is especially so for health care services provided by Columbus Public Health. Our clinics are often providers of last resort, serving patients who have no other options to receive care. Many of the clinics' patients come from historically marginalized communities. Medical mistrust can be even more common in communities of color and other communities that have been negatively affected by historical and current health care disparities.

21. Many Columbus Public Health patients use our services because of the confidentiality they expect to receive from a community-based health center. Many of our patients seek treatment for sexually transmitted infections, substance abuse, and other forms of health care they fear may subject them to stigma. Even if they have family doctors, some patients—survivors of intimate partner violence or sex trafficking, and other vulnerable patients—seek our care because of the guarantee of confidentiality we can provide.

22. Without the protection of HIPAA and its regulations, some of our patients would be less likely to seek care.

23. Fostering trust between clinicians and patients is also important to our public health mission. Accurate medical records assist Columbus Public Health in identifying

problematic trends in public health and in evaluating the effectiveness of various public health programs. Policies that undermine the willingness of patients to share complete and accurate health information with providers undermine the overall objective of public health departments and can have negative impacts on a department's efforts to address community health concerns, like communicable diseases and vaccinations.

24. The 2024 Rule placed important restrictions on using and disclosing information about a patient's reproductive health care. Columbus Public Health's Women's Health and Wellness Center and Sexual Health and Wellness Center provide reproductive health services on a regular basis. The 2024 Rule provided Columbus Public Health's clinics with clarity on how to manage this particularly sensitive patient information. If the 2024 Rule is vacated, it is likely that some patients seeking reproductive health care would forgo such care, and that other patients would withhold critical reproductive health information relevant for proper medical treatment from their clinicians.

25. Since the finalization of the 2024 Rule in April 2024, and in anticipation of the December 23, 2024 compliance deadline, Columbus Public Health has tracked developments regarding new requirements and employees have spent time ensuring that our processes reflect the 2024 Rule's requirements. In preparation for the compliance deadline, our HIPAA Privacy and Security Office has created our HIPAA attestation form and discussed changes to our practices with managers affected by the 2024 Rule.

26. Without the protection of the 2024 Privacy Rule, it would be more difficult for Columbus Public Health providers to protect the sensitive medical information they receive from misuse. In turn, they may lose the trust of their patients, who would fear the release of their private information and be unwilling to be honest with providers or may choose not to seek

treatment all together. Without the 2024 Privacy Rule, Columbus Public Health will face increased challenges to providing effective care to patients and to identifying and addressing troubling health trends in the community. In addition, Columbus Public Health would need to expend staff time and resources to account for and address this development in patient privacy.

(signature on following page)

Executed on February 6, 2025



EDWARD JOHNSON

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI**

STATE OF MISSOURI,

Plaintiff,

v.

No. 4:25-cv-00077

**U.S. DEPARTMENT OF HEALTH &
HUMAN SERVICES, et al.,**

Defendants.

DECLARATION OF JANEL HEINRICH

I, JANEL HEINRICH, hereby declare under penalty of perjury as prescribed in 28 U.S.C. § 1746 that the following is true and correct:

1. My name is Janel Heinrich. I am over eighteen years old, of sound mind, and fully competent to make this declaration. I also have personal knowledge of the factual statements contained herein. I provide this declaration in support of the motion for intervention.

2. I am currently the Director of Public Health Madison and Dane County. I have held that position since I was appointed to it pursuant to Wis. Stat. § 62.51 and Wis. Stat. § 251.06(4)(a) by the Mayor of the City of Madison and the Dane County Executive and confirmed by a vote of the Common Council of Madison and County Board. I have served in this position for more than 14 years.

3. In my position as the Director of Public Health, I serve as the “local health officer” for the City of Madison and the County of Dane under Wis. Stat. § 251.06. This position carries many responsibilities, including but not limited to administering the department, enforcing state public health statutes, and providing information to the public “as to the causes, nature and prevention of prevalent diseases, and the preservation and improvement of health.”

Madison and Public Health Madison and Dane County

4. The City of Madison, Wisconsin, is a municipal corporation organized under Wisconsin law. Wis. Stat. Ch. 66. Madison has all the powers of local self-government and home rule under the constitution and laws of the state of Wisconsin.

5. Madison, located in Dane County, is the capital of Wisconsin. It is the second largest city in the state, with a population of over 269,000, according to 2020 Census estimates.

6. Madison provides a wide range of services on behalf of its residents, including health services for families and children, public health, and emergency medical care. It carries out these essential duties in part through Public Health Madison and Dane County.

7. Public Health Madison and Dane County is an agency with the mission of “working with the community to enhance, protect, and promote the health of the environment and the well-being of all people.” We work to ensure that the Madison and Dane County community is protected from disease and other public health threats and that our residents are empowered to live healthier lives.

8. Public Health Madison and Dane County employs over 200 people operating several public health programs and providing critical services to residents. These programs and services include sexual and reproductive health testing, testing and treatment for tuberculosis, cancer screening, immunizations, treatment for sexually transmitted infections, Nurse Family

Partnership providing home visits for maternal and infant health, and communicable disease testing, among others.

9. Because our mission encompasses the health of the entire community, our programs not only provide treatment to our community, but also prevention and improvement of health outcomes.

10. Public Health Madison and Dane County operates a number of outpatient clinics where staff treat thousands of patients per year. At least 2000 patients sought sexual or reproductive health services at our clinics in the past year.

11. Public Health Madison and Dane County clinics accept and bill public insurers for patients who have health insurance. Clinics provide services to both uninsured and underinsured patients.

12. Public Health Madison and Dane County serves the community regardless of ability to pay. Our clinics are often providers of last resort, serving the city's most vulnerable populations.

13. A critical part of our work relates to the provision of reproductive and sexual health care services. These services enable every Madison resident to make and carry out their own reproductive decisions consistent with Wisconsin law.

14. Public Health Madison and Dane County operates a sexual health clinic, where we provide reproductive health care; testing, treatment and prevention education for sexually transmitted infections; immunizations; contraceptive services; pregnancy testing; and other medical services.

Public Health and HIPAA Privacy Protections

15. Public Health Madison and Dane County is a covered entity under the Health Insurance Portability and Accountability Act (“HIPAA”) and its regulations. Public Health Madison and Dane County is impacted by any changes to HIPAA and its regulations, which it has relied upon for decades.

16. Patient privacy is foundational to Public Health Madison and Dane County’s work. We regularly train all our employees on HIPAA compliance, regardless of whether they work in a clinical setting.

17. HIPAA and its regulations, including the 2024 HIPAA Reproductive Health Rule (“2024 Rule”), have made the work of Public Health Madison and Dane County stronger and better. The presence of national baseline requirements regarding the use and disclosure of patient information helps Public Health Madison and Dane County providers stay confident that they are appropriately safeguarding patient information and adhering to their ethical obligations to do so.

18. In the event of requests for information from third parties, for example, Public Health Madison and Dane County can rely on HIPAA to disclose medical information in a way that appropriately protects patient information.

19. Our patients expect confidentiality as part of our services, and we have a reputation of trust in our community. Our clinicians, patients and community have relied on the protections established by HIPAA privacy practices for more than two decades.

20. HIPAA’s privacy protections help us maintain trust between our clinicians and our patients. Privacy is necessary for the efficient and effective delivery of health care because trust and confidentiality are at the very core of the provider-patient relationship, and those relationships, and the health care system as a whole, are built upon the willingness of individuals

to share the most intimate details of their lives with their health care providers. If patients are not confident in the privacy of their medical information, they will not disclose as much to their providers.

21. HIPAA is a key tool for assuring patients that their medical information will be protected, which increases patient trust, encourages patients to be open and honest with their clinicians, and, in turn, allows us to give them the best possible care.

22. This is especially so for health care services provided by Public Health Madison and Dane County. As providers of last resort, we serve patients who often have no other options to receive care. Many of the clinics' patients come from historically marginalized communities, including immigrant community members. Medical mistrust can be even more common in communities of color and other communities that have been negatively affected by historical and current health care disparities.

23. Public Health Madison and Dane County provides services to all, no matter what their background or circumstances. Many of our patients are only willing to seek care with us because of the confidentiality they expect to receive from a community-based health center, especially patients who seek treatment for sexually transmitted infections and other forms of health care they fear may subject them to stigma.

24. Even if they have family doctors, some patients – survivors of intimate partner violence, minors facing difficult or even dangerous circumstances, and other vulnerable patients, for example – seek our care because of the guarantee of confidentiality we can provide.

25. Public Health Madison and Dane County is trusted in our community and we have support for the work we do. The HIPAA privacy rules are part and parcel to this reputation. They help us maintain trusting relationships between patients from historically disadvantaged

communities and their clinical providers. The importance of this trust relationship is heightened for us as a governmental entity, where many may hold fears associated with seeking help from or sharing information with the government.

26. Fostering trust between clinicians and patients is important to Public Health Madison and Dane County both as a provider of direct services and as the public health authority for the City of Madison. Accurate medical records assist communities in identifying troubling public health trends and in evaluating the effectiveness of various public health efforts. Policies that undermine the willingness of individuals to provide complete and accurate health information to providers undermine the overall objective of public health departments and can have negative impacts on a department's efforts to address community health concerns, like communicable diseases and vaccinations.

27. The 2024 Rule put in place important restrictions on sharing patient information about their reproductive health care, providing Public Health Madison and Dane County's clinics with clarity on how they can use and disclose this particularly sensitive patient information. Public Health Madison and Dane County's Sexual Health Clinic provides reproductive health services on a regular basis. Clinics and clinicians may obtain sensitive reproductive or sexual health information about their patients' medical care in the course of providing treatment wholly unrelated to reproductive or sexual health and record that information in the medical record.

28. If the 2024 Rule is vacated, it is likely that some patients seeking reproductive health care would forgo such care, and that patients will withhold critical reproductive health information relevant for proper medical treatment from their clinicians. Public Health Madison and Dane County would face increased challenges to provide effective care to patients and to identify and address troubling health trends in the community. Without these protections, health

care professionals, such as those employed by Public Health Madison and Dane County, lose the trust of their patients and cannot deliver high-quality care. In turn, Public Health Madison and Dane County would need to expend staff time and resources to account for and address this development in patient privacy.

(signature on following page)

Executed on February 6, 2025



JANEL HEINRICH

PL 104-191, August 21, 1996, 110 Stat 1936

UNITED STATES PUBLIC LAWS

104th Congress - Second Session

Convening January 3, 1996

Additions and Deletions are not identified in this document.

8848

PL 104-191 (HR 3103)

August 21, 1996

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

An Act to amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

<< 42 USCA § 210 NOTE >>

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Health Insurance Portability and Accountability Act of 1996”.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—HEALTH CARE ACCESS, PORTABILITY, AND RENEWABILITY

Subtitle A—Group Market Rules

PART 1—PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS

Sec. 101. Through the Employee Retirement Income Security Act of 1974.

“PART 7—GROUP HEALTH PLAN PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS

“Sec. 701. Increased portability through limitation on preexisting condition exclusions.

“Sec. 702. Prohibiting discrimination against individual participants and beneficiaries based on health status.

“Sec. 703. Guaranteed renewability in multiemployer plans and multiple employer welfare arrangements.

“Sec. 704. Preemption; State flexibility; construction.

“Sec. 705. Special rules relating to group health plans.

“Sec. 706. Definitions.

“Sec. 707. Regulations.”.

Sec. 102. Through the Public Health Service Act.

“TITLE XXVII—ASSURING PORTABILITY, AVAILABILITY,
AND RENEWABILITY OF HEALTH INSURANCE COVERAGE

“PART A—GROUP MARKET REFORMS

“Subpart 1—Portability, Access, and Renewability Requirements

“Sec. 2701. Increased portability through limitation on preexisting condition exclusions.

“Sec. 2702. Prohibiting discrimination against individual participants and beneficiaries based on health status.

“Subpart 2—Provisions Applicable Only to Health Insurance Issuers

“Sec. 2711. Guaranteed availability of coverage for employers in the group market.

“Sec. 2712. Guaranteed renewability of coverage for employers in the group market.

“Sec. 2713. Disclosure of information.

“Subpart 3—Exclusion of Plans; Enforcement; Preemption

“Sec. 2721. Exclusion of certain plans.

“Sec. 2722. Enforcement.

“Sec. 2723. Preemption; State flexibility; construction.

“PART C—DEFINITIONS; MISCELLANEOUS PROVISIONS

“Sec. 2791. Definitions.

“Sec. 2792. Regulations.”.

Sec. 103. Reference to implementation through the Internal Revenue Code of 1986.

Sec. 104. Assuring coordination.

Subtitle B—Individual Market Rules

Sec. 111. Amendment to Public Health Service Act.

“PART B—INDIVIDUAL MARKET RULES

“Sec. 2741. Guaranteed availability of individual health insurance coverage to certain individuals with prior group coverage.

“Sec. 2742. Guaranteed renewability of individual health insurance coverage.

“Sec. 2743. Certification of coverage.

“Sec. 2744. State flexibility in individual market reforms.

“Sec. 2745. Enforcement.

“Sec. 2746. Preemption.

“Sec. 2747. General exceptions.”.

Subtitle C—General and Miscellaneous Provisions

Sec. 191. Health coverage availability studies.

Sec. 192. Report on Medicare reimbursement of telemedicine.

Sec. 193. Allowing federally-qualified HMOs to offer high deductible plans.

Sec. 194. Volunteer services provided by health professionals at free clinics.

Sec. 195. Findings; severability.

TITLE II—PREVENTING HEALTH CARE FRAUD AND ABUSE;
ADMINISTRATIVE SIMPLIFICATION; MEDICAL LIABILITY REFORM

Sec. 200. References in title.

Subtitle A—Fraud and Abuse Control Program

Sec. 201. Fraud and abuse control program.

Sec. 202. Medicare integrity program.

Sec. 203. Beneficiary incentive programs.

Sec. 204. Application of certain health antifraud and abuse sanctions to fraud and abuse against Federal health care programs.

Sec. 205. Guidance regarding application of health care fraud and abuse sanctions.

Subtitle B—Revisions to Current Sanctions for Fraud and Abuse

Sec. 211. Mandatory exclusion from participation in Medicare and State health care programs.

Sec. 212. Establishment of minimum period of exclusion for certain individuals and entities subject to permissive exclusion from Medicare and State health care programs.

Sec. 213. Permissive exclusion of individuals with ownership or control interest in sanctioned entities.

Sec. 214. Sanctions against practitioners and persons for failure to comply with statutory obligations.

Sec. 215. Intermediate sanctions for Medicare health maintenance organizations.

Sec. 216. Additional exception to anti-kickback penalties for risk-sharing arrangements.

Sec. 217. Criminal penalty for fraudulent disposition of assets in order to obtain medicaid benefits.

Sec. 218. Effective date.

Subtitle C—Data Collection

Sec. 221. Establishment of the health care fraud and abuse data collection program.

Subtitle D—Civil Monetary Penalties

Sec. 231. Social Security Act civil monetary penalties.

Sec. 232. Penalty for false certification for home health services.

Subtitle E—Revisions to Criminal Law

Sec. 241. Definitions relating to Federal health care offense.

Sec. 242. Health care fraud.

Sec. 243. Theft or embezzlement.

Sec. 244. False statements.

Sec. 245. Obstruction of criminal investigations of health care offenses.

Sec. 246. Laundering of monetary instruments.

Sec. 247. Injunctive relief relating to health care offenses.

Sec. 248. Authorized investigative demand procedures.

Sec. 249. Forfeitures for Federal health care offenses.

Sec. 250. Relation to ERISA authority.

Subtitle F—Administrative Simplification

Sec. 261. Purpose.

Sec. 262. Administrative simplification.

“PART C—ADMINISTRATIVE SIMPLIFICATION

“Sec. 1171. Definitions.

“Sec. 1172. General requirements for adoption of standards.

“Sec. 1173. Standards for information transactions and data elements.

“Sec. 1174. Timetables for adoption of standards.

“Sec. 1175. Requirements.

“Sec. 1176. General penalty for failure to comply with requirements and standards.

“Sec. 1177. Wrongful disclosure of individually identifiable health information.

“Sec. 1178. Effect on State law.

“Sec. 1179. Processing payment transactions.”.

Sec. 263. Changes in membership and duties of National Committee on Vital and Health Statistics.

Sec. 264. Recommendations with respect to privacy of certain health information.

Subtitle G—Duplication and Coordination of Medicare-Related Plans.

Sec. 271. Duplication and coordination of Medicare-related plans.

TITLE III—TAX-RELATED HEALTH PROVISIONS

Sec. 300. Amendment of 1986 Code.

Subtitle A—Medical Savings Accounts

Sec. 301. Medical savings accounts.

Subtitle B—Increase in Deduction for Health Insurance Costs of Self-Employed Individuals

Sec. 311. Increase in deduction for health insurance costs of self-employed individuals.

Subtitle C—Long-Term Care Services and Contracts

PART I—GENERAL PROVISIONS

Sec. 321. Treatment of long-term care insurance.

Sec. 322. Qualified long-term care services treated as medical care.

Sec. 323. Reporting requirements.

PART II—CONSUMER PROTECTION PROVISIONS

Sec. 325. Policy requirements.

Sec. 326. Requirements for issuers of qualified long-term care insurance contracts.

Sec. 327. Effective dates.

Subtitle D—Treatment of Accelerated Death Benefits

Sec. 331. Treatment of accelerated death benefits by recipient.

Sec. 332. Tax treatment of companies issuing qualified accelerated death benefit riders.

Subtitle E—State Insurance Pools

Sec. 341. Exemption from income tax for State-sponsored organizations providing health coverage for high-risk individuals.

Sec. 342. Exemption from income tax for State-sponsored workmen's compensation reinsurance organizations.

Subtitle F—Organizations Subject to Section 833

Sec. 351. Organizations subject to section 833.

Subtitle G—IRA Distributions to the Unemployed

Sec. 361. Distributions from certain plans may be used without additional tax to pay financially devastating medical expenses.

Subtitle H—Organ and Tissue Donation Information Included With Income Tax Refund Payments

Sec. 371. Organ and tissue donation information included with income tax refund payments.

TITLE IV—APPLICATION AND ENFORCEMENT OF GROUP HEALTH PLAN REQUIREMENTS

Subtitle A—Application and Enforcement of Group Health Plan Requirements

Sec. 401. Group health plan portability, access, and renewability requirements.

Sec. 402. Penalty on failure to meet certain group health plan requirements.

Subtitle B—Clarification of Certain Continuation Coverage Requirements

Sec. 421. COBRA clarifications.

TITLE V—REVENUE OFFSETS

Sec. 500. Amendment of 1986 Code.

Subtitle A—Company-Owned Life Insurance

Sec. 501. Denial of deduction for interest on loans with respect to company-owned life insurance.

Subtitle B—Treatment of Individuals Who Lose United States Citizenship

Sec. 511. Revision of income, estate, and gift taxes on individuals who lose United States citizenship.

Sec. 512. Information on individuals losing United States citizenship.

Sec. 513. Report on tax compliance by United States citizens and residents living abroad.

Subtitle C—Repeal of Financial Institution Transition Rule to Interest Allocation Rules

Sec. 521. Repeal of financial institution transition rule to interest allocation rules.

TITLE I—HEALTH CARE ACCESS, PORTABILITY, AND RENEWABILITY

Subtitle A—Group Market Rules

PART 1—PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS

SEC. 101. THROUGH THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) IN GENERAL.—Subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new part:

<< 29 USCA Ch. 18 >>

“PART 7—GROUP HEALTH PLAN PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS

<< 29 USCA § 1181 >>

“SEC. 701. INCREASED PORTABILITY THROUGH LIMITATION ON PREEXISTING CONDITION EXCLUSIONS.

“(a) LIMITATION ON PREEXISTING CONDITION EXCLUSION PERIOD; CREDITING FOR PERIODS OF PREVIOUS COVERAGE.—Subject to subsection (d), a group health plan, and a health insurance issuer offering group health insurance coverage, may, with respect to a participant or beneficiary, impose a preexisting condition exclusion only if—

“(1) such exclusion relates to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6-month period ending on the enrollment date;

“(2) such exclusion extends for a period of not more than 12 months (or 18 months in the case of a late enrollee) after the enrollment date; and

“(3) the period of any such preexisting condition exclusion is reduced by the aggregate of the periods of creditable coverage (if any, as defined in subsection (c)(1)) applicable to the participant or beneficiary as of the enrollment date.

“(b) DEFINITIONS.—For purposes of this part—

“(1) PREEXISTING CONDITION EXCLUSION.—

“(A) IN GENERAL.—The term ‘preexisting condition exclusion’ means, with respect to coverage, a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.

“(B) TREATMENT OF GENETIC INFORMATION.—Genetic information shall not be treated as a condition described in subsection (a)(1) in the absence of a diagnosis of the condition related to such information.

“(2) ENROLLMENT DATE.—The term ‘enrollment date’ means, with respect to an individual covered under a group health plan or health insurance coverage, the date of enrollment of the individual in the plan or coverage or, if earlier, the first day of the waiting period for such enrollment.

“(3) LATE ENROLLEE.—The term ‘late enrollee’ means, with respect to coverage under a group health plan, a participant or beneficiary who enrolls under the plan other than during—

“(A) the first period in which the individual is eligible to enroll under the plan, or

“(B) a special enrollment period under subsection (f).

“(4) WAITING PERIOD.—The term ‘waiting period’ means, with respect to a group health plan and an individual who is a potential participant or beneficiary in the plan, the period that must pass with respect to the individual before the individual is eligible to be covered for benefits under the terms of the plan.

“(c) RULES RELATING TO CREDITING PREVIOUS COVERAGE.—

“(1) CREDITABLE COVERAGE DEFINED.—For purposes of this part, the term ‘creditable coverage’ means, with respect to an individual, coverage of the individual under any of the following:

“(A) A group health plan.

“(B) Health insurance coverage.

“(C) Part A or part B of title XVIII of the Social Security Act.

“(D) Title XIX of the Social Security Act, other than coverage consisting solely of benefits under section 1928.

“(E) Chapter 55 of title 10, United States Code.

“(F) A medical care program of the Indian Health Service or of a tribal organization.

“(G) A State health benefits risk pool.

“(H) A health plan offered under chapter 89 of title 5, United States Code.

“(I) A public health plan (as defined in regulations).

“(J) A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

Such term does not include coverage consisting solely of coverage of excepted benefits (as defined in section 706(c)).

“(2) NOT COUNTING PERIODS BEFORE SIGNIFICANT BREAKS IN COVERAGE.—

“(A) IN GENERAL.—A period of creditable coverage shall not be counted, with respect to enrollment of an individual under a group health plan, if, after such period and before the enrollment date, there was a 63-day period during all of which the individual was not covered under any creditable coverage.

“(B) WAITING PERIOD NOT TREATED AS A BREAK IN COVERAGE.—For purposes of subparagraph (A) and subsection (d)(4), any period that an individual is in a waiting period for any coverage under a group health plan (or for group health insurance coverage) or is in an affiliation period (as defined in subsection (g)(2)) shall not be taken into account in determining the continuous period under subparagraph (A).

“(3) METHOD OF CREDITING COVERAGE.—

“(A) STANDARD METHOD.—Except as otherwise provided under subparagraph (B), for purposes of applying subsection (a)(3), a group health plan, and a health insurance issuer offering group health insurance coverage, shall count a period of creditable coverage without regard to the specific benefits covered during the period.

“(B) ELECTION OF ALTERNATIVE METHOD.—A group health plan, or a health insurance issuer offering group health insurance coverage, may elect to apply subsection (a)(3) based on coverage of benefits within each of several classes or categories of benefits specified in regulations rather than as provided under subparagraph (A). Such election shall be made on a uniform basis for all participants and beneficiaries. Under such election a group health plan or issuer shall count a period of creditable coverage with respect to any class or category of benefits if any level of benefits is covered within such class or category.

“(C) PLAN NOTICE.—In the case of an election with respect to a group health plan under subparagraph (B) (whether or not health insurance coverage is provided in connection with such plan), the plan shall—

“(i) prominently state in any disclosure statements concerning the plan, and state to each enrollee at the time of enrollment under the plan, that the plan has made such election, and

“(ii) include in such statements a description of the effect of this election.

“(4) ESTABLISHMENT OF PERIOD.—Periods of creditable coverage with respect to an individual shall be established through presentation of certifications described in subsection (e) or in such other manner as may be specified in regulations.

“(d) EXCEPTIONS.—

“(1) EXCLUSION NOT APPLICABLE TO CERTAIN NEWBORNS.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion in the case of an individual who, as of the last day of the 30-day period beginning with the date of birth, is covered under creditable coverage.

“(2) EXCLUSION NOT APPLICABLE TO CERTAIN ADOPTED CHILDREN.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion in the case of a child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30-day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. The previous sentence shall not apply to coverage before the date of such adoption or placement for adoption.

“(3) EXCLUSION NOT APPLICABLE TO PREGNANCY.—A group health plan, and health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion relating to pregnancy as a preexisting condition.

“(4) LOSS IF BREAK IN COVERAGE.—Paragraphs (1) and (2) shall no longer apply to an individual after the end of the first 63-day period during all of which the individual was not covered under any creditable coverage.

“(e) CERTIFICATIONS AND DISCLOSURE OF COVERAGE.—

“(1) REQUIREMENT FOR CERTIFICATION OF PERIOD OF CREDITABLE COVERAGE.—

“(A) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide the certification described in subparagraph (B)—

“(i) at the time an individual ceases to be covered under the plan or otherwise becomes covered under a COBRA continuation provision,

“(ii) in the case of an individual becoming covered under such a provision, at the time the individual ceases to be covered under such provision, and

“(iii) on the request on behalf of an individual made not later than 24 months after the date of cessation of the coverage described in clause (i) or (ii), whichever is later.

The certification under clause (i) may be provided, to the extent practicable, at a time consistent with notices required under any applicable COBRA continuation provision.

“(B) CERTIFICATION.—The certification described in this subparagraph is a written certification of—

“(i) the period of creditable coverage of the individual under such plan and the coverage (if any) under such COBRA continuation provision, and

“(ii) the waiting period (if any) (and affiliation period, if applicable) imposed with respect to the individual for any coverage under such plan.

“(C) ISSUER COMPLIANCE.—To the extent that medical care under a group health plan consists of group health insurance coverage, the plan is deemed to have satisfied the certification requirement under this paragraph if the health insurance issuer offering the coverage provides for such certification in accordance with this paragraph.

“(2) DISCLOSURE OF INFORMATION ON PREVIOUS BENEFITS.—In the case of an election described in subsection (c)(3)(B) by a group health plan or health insurance issuer, if the plan or issuer enrolls an individual for coverage under the plan and the individual provides a certification of coverage of the individual under paragraph (1)—

“(A) upon request of such plan or issuer, the entity which issued the certification provided by the individual shall promptly disclose to such requesting plan or issuer information on coverage of classes and categories of health benefits available under such entity's plan or coverage, and

“(B) such entity may charge the requesting plan or issuer for the reasonable cost of disclosing such information.

“(3) REGULATIONS.—The Secretary shall establish rules to prevent an entity's failure to provide information under paragraph (1) or (2) with respect to previous coverage of an individual from adversely affecting any subsequent coverage of the individual under another group health plan or health insurance coverage.

“(f) SPECIAL ENROLLMENT PERIODS.—

“(1) INDIVIDUALS LOSING OTHER COVERAGE.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if each of the following conditions is met:

“(A) The employee or dependent was covered under a group health plan or had health insurance coverage at the time coverage was previously offered to the employee or dependent.

“(B) The employee stated in writing at such time that coverage under a group health plan or health insurance coverage was the reason for declining enrollment, but only if the plan sponsor or issuer (if applicable) required such a statement at such time and provided the employee with notice of such requirement (and the consequences of such requirement) at such time.

“(C) The employee's or dependent's coverage described in subparagraph (A)—

“(i) was under a COBRA continuation provision and the coverage under such provision was exhausted; or

“(ii) was not under such a provision and either the coverage was terminated as a result of loss of eligibility for the coverage (including as a result of legal separation, divorce, death, termination of employment, or reduction in the number of hours of employment) or employer contributions toward such coverage were terminated.

“(D) Under the terms of the plan, the employee requests such enrollment not later than 30 days after the date of exhaustion of coverage described in subparagraph (C)(i) or termination of coverage or employer contribution described in subparagraph (C)(ii).

“(2) FOR DEPENDENT BENEFICIARIES.—

“(A) IN GENERAL.—If—

“(i) a group health plan makes coverage available with respect to a dependent of an individual,

“(ii) the individual is a participant under the plan (or has met any waiting period applicable to becoming a participant under the plan and is eligible to be enrolled under the plan but for a failure to enroll during a previous enrollment period), and

“(iii) a person becomes such a dependent of the individual through marriage, birth, or adoption or placement for adoption,

the group health plan shall provide for a dependent special enrollment period described in subparagraph (B) during which the person (or, if not otherwise enrolled, the individual) may be enrolled under the plan as a dependent of the individual, and in the case of the birth or adoption of a child, the spouse of the individual may be enrolled as a dependent of the individual if such spouse is otherwise eligible for coverage.

“(B) DEPENDENT SPECIAL ENROLLMENT PERIOD.—A dependent special enrollment period under this subparagraph shall be a period of not less than 30 days and shall begin on the later of—

“(i) the date dependent coverage is made available, or

“(ii) the date of the marriage, birth, or adoption or placement for adoption (as the case may be) described in subparagraph (A)(iii).

“(C) NO WAITING PERIOD.—If an individual seeks to enroll a dependent during the first 30 days of such a dependent special enrollment period, the coverage of the dependent shall become effective—

“(i) in the case of marriage, not later than the first day of the first month beginning after the date the completed request for enrollment is received;

“(ii) in the case of a dependent's birth, as of the date of such birth; or

“(iii) in the case of a dependent's adoption or placement for adoption, the date of such adoption or placement for adoption.

“(g) USE OF AFFILIATION PERIOD BY HMOS AS ALTERNATIVE TO PREEXISTING CONDITION EXCLUSION.—

“(1) IN GENERAL.—In the case of a group health plan that offers medical care through health insurance coverage offered by a health maintenance organization, the plan may provide for an affiliation period with respect to coverage through the organization only if—

“(A) no preexisting condition exclusion is imposed with respect to coverage through the organization,

“(B) the period is applied uniformly without regard to any health status-related factors, and

“(C) such period does not exceed 2 months (or 3 months in the case of a late enrollee).

“(2) AFFILIATION PERIOD.—

“(A) DEFINED.—For purposes of this part, the term ‘affiliation period’ means a period which, under the terms of the health insurance coverage offered by the health maintenance organization, must expire before the health insurance coverage becomes effective. The organization is not required to provide health care services or benefits during such period and no premium shall be charged to the participant or beneficiary for any coverage during the period.

“(B) BEGINNING.—Such period shall begin on the enrollment date.

“(C) RUNS CONCURRENTLY WITH WAITING PERIODS.—An affiliation period under a plan shall run concurrently with any waiting period under the plan.

“(3) ALTERNATIVE METHODS.—A health maintenance organization described in paragraph (1) may use alternative methods, from those described in such paragraph, to address adverse selection as approved by the State insurance commissioner or official or officials designated by the State to enforce the requirements of part A of title XXVII of the Public Health Service Act for the State involved with respect to such issuer.

<< 29 USCA § 1182 >>

“SEC. 702. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

“(a) IN ELIGIBILITY TO ENROLL.—

“(1) IN GENERAL.—Subject to paragraph (2), a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

“(A) Health status.

“(B) Medical condition (including both physical and mental illnesses).

“(C) Claims experience.

“(D) Receipt of health care.

“(E) Medical history.

“(F) Genetic information.

“(G) Evidence of insurability (including conditions arising out of acts of domestic violence).

“(H) Disability.

“(2) NO APPLICATION TO BENEFITS OR EXCLUSIONS.—To the extent consistent with section 701, paragraph (1) shall not be construed—

“(A) to require a group health plan, or group health insurance coverage, to provide particular benefits other than those provided under the terms of such plan or coverage, or

“(B) to prevent such a plan or coverage from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

“(3) CONSTRUCTION.—For purposes of paragraph (1), rules for eligibility to enroll under a plan include rules defining any applicable waiting periods for such enrollment.

“(b) IN PREMIUM CONTRIBUTIONS.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

“(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

“(A) to restrict the amount that an employer may be charged for coverage under a group health plan; or

“(B) to prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

<< 29 USCA § 1183 >>

“SEC. 703. GUARANTEED RENEWABILITY IN MULTIEMPLOYER PLANS AND MULTIPLE EMPLOYER WELFARE ARRANGEMENTS.

“A group health plan which is a multiemployer plan or which is a multiple employer welfare arrangement may not deny an employer whose employees are covered under such a plan continued access to the same or different coverage under the terms of such a plan, other than—

“(1) for nonpayment of contributions;

“(2) for fraud or other intentional misrepresentation of material fact by the employer;

“(3) for noncompliance with material plan provisions;

“(4) because the plan is ceasing to offer any coverage in a geographic area;

“(5) in the case of a plan that offers benefits through a network plan, there is no longer any individual enrolled through the employer who lives, resides, or works in the service area of the network plan and the plan applies this paragraph uniformly without regard to the claims experience of employers or any health status-related factor in relation to such individuals or their dependents; and

“(6) for failure to meet the terms of an applicable collective bargaining agreement, to renew a collective bargaining or other agreement requiring or authorizing contributions to the plan, or to employ employees covered by such an agreement.

<< 29 USCA § 1184 >>

“SEC. 704. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

“(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

“(1) IN GENERAL.—Subject to paragraph (2) and except as provided in subsection (b), this part shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part.

“(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this part shall be construed to affect or modify the provisions of section 514 with respect to group health plans.

“(b) SPECIAL RULES IN CASE OF PORTABILITY REQUIREMENTS.—

“(1) IN GENERAL.—Subject to paragraph (2), the provisions of this part relating to health insurance coverage offered by a health insurance issuer supersede any provision of State law which establishes, implements, or continues in effect a standard or requirement applicable to imposition of a preexisting condition exclusion specifically governed by section 701 which differs from the standards or requirements specified in such section.

“(2) EXCEPTIONS.—Only in relation to health insurance coverage offered by a health insurance issuer, the provisions of this part do not supersede any provision of State law to the extent that such provision—

“(A) substitutes for the reference to ‘6-month period’ in section 701(a)(1) a reference to any shorter period of time;

“(B) substitutes for the reference to ‘12 months’ and ‘18 months’ in section 701(a)(2) a reference to any shorter period of time;

“(C) substitutes for the references to ‘63 days’ in sections 701(c)(2)(A) and (d)(4)(A) a reference to any greater number of days;

“(D) substitutes for the reference to ‘30-day period’ in sections 701(b)(2) and (d)(1) a reference to any greater period;

“(E) prohibits the imposition of any preexisting condition exclusion in cases not described in section 701(d) or expands the exceptions described in such section;

“(F) requires special enrollment periods in addition to those required under section 701(f); or

“(G) reduces the maximum period permitted in an affiliation period under section 701(g)(1)(B).

“(c) RULES OF CONSTRUCTION.—Nothing in this part shall be construed as requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

“(d) DEFINITIONS.—For purposes of this section—

“(1) STATE LAW.—The term ‘State law’ includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

“(2) STATE.—The term ‘State’ includes a State, the Northern Mariana Islands, any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

<< 29 USCA § 1185 >>

“SEC. 705. SPECIAL RULES RELATING TO GROUP HEALTH PLANS.

“(a) GENERAL EXCEPTION FOR CERTAIN SMALL GROUP HEALTH PLANS.—The requirements of this part shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees.

“(b) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of this part shall not apply to any group health plan (and group health insurance coverage) in relation to its provision of excepted benefits described in section 706(c)(1).

“(c) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—

“(1) LIMITED, EXCEPTED BENEFITS.—The requirements of this part shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 706(c)(2) if the benefits—

“(A) are provided under a separate policy, certificate, or contract of insurance; or

“(B) are otherwise not an integral part of the plan.

“(2) NONCOORDINATED, EXCEPTED BENEFITS.—The requirements of this part shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 706(c)(3) if all of the following conditions are met:

“(A) The benefits are provided under a separate policy, certificate, or contract of insurance.

“(B) There is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor.

“(C) Such benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor.

“(3) SUPPLEMENTAL EXCEPTED BENEFITS.—The requirements of this part shall not apply to any group health plan (and group health insurance coverage) in relation to its provision of excepted benefits described in section 706(c)(4) if the benefits are provided under a separate policy, certificate, or contract of insurance.

“(d) TREATMENT OF PARTNERSHIPS.—For purposes of this part—

“(1) TREATMENT AS A GROUP HEALTH PLAN.—Any plan, fund, or program which would not be (but for this subsection) an employee welfare benefit plan and which is established or maintained by a partnership, to the extent that such plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, shall be treated (subject to paragraph (2)) as an employee welfare benefit plan which is a group health plan.

“(2) EMPLOYER.—In the case of a group health plan, the term ‘employer’ also includes the partnership in relation to any partner.

“(3) PARTICIPANTS OF GROUP HEALTH PLANS.—In the case of a group health plan, the term ‘participant’ also includes —

“(A) in connection with a group health plan maintained by a partnership, an individual who is a partner in relation to the partnership, or

“(B) in connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the self-employed individual,

if such individual is, or may become, eligible to receive a benefit under the plan or such individual's beneficiaries may be eligible to receive any such benefit.

<< 29 USCA § 1186 >>

“SEC. 706. DEFINITIONS.

“(a) GROUP HEALTH PLAN.—For purposes of this part—

“(1) IN GENERAL.—The term ‘group health plan’ means an employee welfare benefit plan to the extent that the plan provides medical care (as defined in paragraph (2) and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

“(2) MEDICAL CARE.—The term ‘medical care’ means amounts paid for—

“(A) the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body,

“(B) amounts paid for transportation primarily for and essential to medical care referred to in subparagraph (A), and

“(C) amounts paid for insurance covering medical care referred to in subparagraphs (A) and (B).

“(b) DEFINITIONS RELATING TO HEALTH INSURANCE.—For purposes of this part—

“(1) HEALTH INSURANCE COVERAGE.—The term ‘health insurance coverage’ means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as medical care) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer.

“(2) HEALTH INSURANCE ISSUER.—The term ‘health insurance issuer’ means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in paragraph (3)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2)). Such term does not include a group health plan.

“(3) HEALTH MAINTENANCE ORGANIZATION.—The term ‘health maintenance organization’ means—

“(A) a federally qualified health maintenance organization (as defined in section 1301(a) of the Public Health Service Act (42 U.S.C. 300e(a))),

“(B) an organization recognized under State law as a health maintenance organization, or

“(C) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

“(4) GROUP HEALTH INSURANCE COVERAGE.—The term ‘group health insurance coverage’ means, in connection with a group health plan, health insurance coverage offered in connection with such plan.

“(c) EXCEPTED BENEFITS.—For purposes of this part, the term ‘excepted benefits’ means benefits under one or more (or any combination thereof) of the following:

“(1) BENEFITS NOT SUBJECT TO REQUIREMENTS.—

“(A) Coverage only for accident, or disability income insurance, or any combination thereof.

“(B) Coverage issued as a supplement to liability insurance.

“(C) Liability insurance, including general liability insurance and automobile liability insurance.

“(D) Workers' compensation or similar insurance.

“(E) Automobile medical payment insurance.

“(F) Credit-only insurance.

“(G) Coverage for on-site medical clinics.

“(H) Other similar insurance coverage, specified in regulations, under which benefits for medical care are secondary or incidental to other insurance benefits.

“(2) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED SEPARATELY.—

“(A) Limited scope dental or vision benefits.

“(B) Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof.

“(C) Such other similar, limited benefits as are specified in regulations.

“(3) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS INDEPENDENT, NONCOORDINATED BENEFITS.—

“(A) Coverage only for a specified disease or illness.

“(B) Hospital indemnity or other fixed indemnity insurance.

“(4) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS SEPARATE INSURANCE POLICY.—Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act), coverage supplemental to the coverage provided under chapter 55 of title 10, United States Code, and similar supplemental coverage provided to coverage under a group health plan.

“(d) OTHER DEFINITIONS.—For purposes of this part—

“(1) COBRA CONTINUATION PROVISION.—The term ‘COBRA continuation provision’ means any of the following:

“(A) Part 6 of this subtitle.

“(B) Section 4980B of the Internal Revenue Code of 1986, other than subsection (f)(1) of such section insofar as it relates to pediatric vaccines.

“(C) Title XXII of the Public Health Service Act.

“(2) HEALTH STATUS-RELATED FACTOR.—The term ‘health status-related factor’ means any of the factors described in section 702(a)(1).

“(3) NETWORK PLAN.—The term ‘network plan’ means health insurance coverage offered by a health insurance issuer under which the financing and delivery of medical care (including items and services paid for as medical care) are provided, in whole or in part, through a defined set of providers under contract with the issuer.

“(4) PLACED FOR ADOPTION.—The term ‘placement’, or being ‘placed’, for adoption, has the meaning given such term in section 609(c)(3)(B).

<< 29 USCA § 1187 >>

“SEC. 707. REGULATIONS.

“The Secretary, consistent with section 104 of the Health Care Portability and Accountability Act of 1996, may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this part. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this part.”.

<< 29 USCA § 1132 >>

(b) ENFORCEMENT WITH RESPECT TO HEALTH INSURANCE ISSUERS.—Section 502(b) of such Act (29 U.S.C. 1132(b)) is amended by adding at the end the following new paragraph:

“(3) The Secretary is not authorized to enforce under this part any requirement of part 7 against a health insurance issuer offering health insurance coverage in connection with a group health plan (as defined in section 706(a)(1)). Nothing in this paragraph shall affect the authority of the Secretary to issue regulations to carry out such part.”.

(c) DISCLOSURE OF INFORMATION TO PARTICIPANTS AND BENEFICIARIES.—

<< 29 USCA § 1024 >>

(1) IN GENERAL.—Section 104(b)(1) of such Act (29 U.S.C. 1024(b)(1)) is amended in the matter following subparagraph (B)—

(A) by striking “102(a)(1),” and inserting “102(a)(1) (other than a material reduction in covered services or benefits provided in the case of a group health plan (as defined in section 706(a)(1))),”; and

(B) by adding at the end the following new sentences: “If there is a modification or change described in section 102(a)(1) that is a material reduction in covered services or benefits provided under a group health plan (as defined in section 706(a)(1)), a summary description of such modification or change shall be furnished to participants and beneficiaries not later than 60 days after the date of the adoption of the modification or change. In the alternative, the plan sponsors may provide such description at regular intervals of not more than 90 days. The Secretary shall issue regulations within 180 days after the date of enactment of the Health Insurance Portability and Accountability Act of 1996, providing alternative mechanisms to delivery by mail through which group health plans (as so defined) may notify participants and beneficiaries of material reductions in covered services or benefits.”.

<< 29 USCA § 1022 >>

(2) PLAN DESCRIPTION AND SUMMARY.—Section 102(b) of such Act (29 U.S.C. 1022(b)) is amended—

(A) by inserting “in the case of a group health plan (as defined in section 706(a)(1)), whether a health insurance issuer (as defined in section 706(b)(2)) is responsible for the financing or administration (including payment of claims) of the plan and (if so) the name and address of such issuer;” after “type of administration of the plan;”; and

(B) by inserting “including the office at the Department of Labor through which participants and beneficiaries may seek assistance or information regarding their rights under this Act and the Health Insurance Portability and Accountability Act of 1996 with respect to health benefits that are offered through a group health plan (as defined in section 706(a)(1))” after “benefits under the plan”.

<< 29 USCA § 1003 >>

(d) TREATMENT OF HEALTH INSURANCE ISSUERS OFFERING HEALTH INSURANCE COVERAGE TO NONCOVERED PLANS.—Section 4(b) of such Act (29 U.S.C. 1003(b)) is amended by adding at the end (after and below paragraph (5)) the following:

“The provisions of part 7 of subtitle B shall not apply to a health insurance issuer (as defined in section 706(b)(2)) solely by reason of health insurance coverage (as defined in section 706(b)(1)) provided by such issuer in connection with a group health plan (as defined in section 706(a)(1)) if the provisions of this title do not apply to such group health plan.”.

(e) REPORTING AND ENFORCEMENT WITH RESPECT TO CERTAIN ARRANGEMENTS.—

<< 29 USCA § 1021 >>

(1) IN GENERAL.—Section 101 of such Act (29 U.S.C. 1021) is amended—

(A) by redesignating subsection (g) as subsection (h), and

(B) by inserting after subsection (f) the following new subsection:

“(g) REPORTING BY CERTAIN ARRANGEMENTS.—The Secretary may, by regulation, require multiple employer welfare arrangements providing benefits consisting of medical care (within the meaning of section 706(a)(2)) which are not group health plans to report, not more frequently than annually, in such form and such manner as the Secretary may require for the purpose of determining the extent to which the requirements of part 7 are being carried out in connection with such benefits.”.

<< 29 USCA § 1132 >>

(2) ENFORCEMENT.—

(A) IN GENERAL.—Section 502 of such Act (29 U.S.C. 1132) is amended—

(i) in subsection (a)(6), by striking “under subsection (c)(2) or (i) or (l)” and inserting “under paragraph (2), (4), or (5) of subsection (c) or under subsection (i) or (l)”; and

(ii) in the last 2 sentences of subsection (c), by striking “For purposes of this paragraph” and all that follows through “The Secretary and” and inserting the following:

“(5) The Secretary may assess a civil penalty against any person of up to \$1,000 a day from the date of the person's failure or refusal to file the information required to be filed by such person with the Secretary under regulations prescribed pursuant to section 101(g).

“(6) The Secretary and”.

(B) TECHNICAL AND CONFORMING AMENDMENT.—Section 502(c)(1) of such Act (29 U.S.C. 1132(c)(1)) is amended by adding at the end the following sentence: “For purposes of this paragraph, each violation described in subparagraph (A) with respect to any single participant, and each violation described in subparagraph (B) with respect to any single participant or beneficiary, shall be treated as a separate violation.”.

<< 29 USCA § 1136 >>

(3) COORDINATION.—Section 506 of such Act (29 U.S.C. 1136) is amended by adding at the end the following new subsection:

“(c) COORDINATION OF ENFORCEMENT WITH STATES WITH RESPECT TO CERTAIN ARRANGEMENTS.—A State may enter into an agreement with the Secretary for delegation to the State of some or all of the Secretary's authority under sections 502 and 504 to enforce the requirements under part 7 in connection with multiple employer welfare arrangements, providing medical care (within the meaning of section 706(a)(2)), which are not group health plans.”.

(f) CONFORMING AMENDMENTS.—

<< 29 USCA § 1144 >>

(1) Section 514(b) of such Act (29 U.S.C. 1144(b)) is amended by adding at the end the following new paragraph:

“(9) For additional provisions relating to group health plans, see section 704.”.

(2)(A) Part 6 of subtitle B of title I of such Act (29 U.S.C. 1161 et seq.) is amended by striking the heading and inserting the following:

<< 29 USCA Ch. 18 >>

“PART 6—CONTINUATION COVERAGE AND ADDITIONAL STANDARDS FOR GROUP HEALTH PLANS”.

(B) The table of contents in section 1 of such Act is amended by striking the item relating to the heading for part 6 of subtitle B of title I and inserting the following:

“PART 6—CONTINUATION COVERAGE AND ADDITIONAL STANDARDS FOR GROUP HEALTH PLANS”.

(3) The table of contents in section 1 of such Act (as amended by the preceding provisions of this section) is amended by inserting after the items relating to part 6 the following new items:

“PART 7—GROUP HEALTH PLAN PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS

“Sec. 701. Increased portability through limitation on preexisting condition exclusions.

“Sec. 702. Prohibiting discrimination against individual participants and beneficiaries based on health status.

“Sec. 703. Guaranteed renewability in multiemployer plans and multiple employer welfare arrangements.

“Sec. 704. Preemption; State flexibility; construction.

“Sec. 705. Special rules relating to group health plans.

“Sec. 706. Definitions.

“Sec. 707. Regulations.”.

<< 29 USCA §§ 1003 nt, 1021 nt, 1022 nt, 1024 nt, 1132 nt, 1136 nt, 1144 nt >>

<< 29 USCA §§ 1181 NOTE, 1182 nt, 1183 nt, 1184 nt, 1185 nt, 1186 nt, 1187 nt >>

(g) EFFECTIVE DATES.—

(1) IN GENERAL.—Except as provided in this section, this section (and the amendments made by this section) shall apply with respect to group health plans for plan years beginning after June 30, 1997.

(2) DETERMINATION OF CREDITABLE COVERAGE.—

(A) PERIOD OF COVERAGE.—

(i) IN GENERAL.—Subject to clause (ii), no period before July 1, 1996, shall be taken into account under part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (as added by this section) in determining creditable coverage.

(ii) SPECIAL RULE FOR CERTAIN PERIODS.—The Secretary of Labor, consistent with section 104, shall provide for a process whereby individuals who need to establish creditable coverage for periods before July 1, 1996, and who would have such coverage credited but for clause (i) may be given credit for creditable coverage for such periods through the presentation of documents or other means.

(B) CERTIFICATIONS, ETC.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), subsection (e) of section 701 of the Employee Retirement Income Security Act of 1974 (as added by this section) shall apply to events occurring after June 30, 1996.

(ii) NO CERTIFICATION REQUIRED TO BE PROVIDED BEFORE JUNE 1, 1997.—In no case is a certification required to be provided under such subsection before June 1, 1997.

(iii) CERTIFICATION ONLY ON WRITTEN REQUEST FOR EVENTS OCCURRING BEFORE OCTOBER 1, 1996.—In the case of an event occurring after June 30, 1996, and before October 1, 1996, a certification is not required to be provided under such subsection unless an individual (with respect to whom the certification is otherwise required to be made) requests such certification in writing.

(C) TRANSITIONAL RULE.—In the case of an individual who seeks to establish creditable coverage for any period for which certification is not required because it relates to an event occurring before June 30, 1996—

(i) the individual may present other credible evidence of such coverage in order to establish the period of creditable coverage; and

(ii) a group health plan and a health insurance issuer shall not be subject to any penalty or enforcement action with respect to the plan's or issuer's crediting (or not crediting) such coverage if the plan or issuer has sought to comply in good faith with the applicable requirements under the amendments made by this section.

(3) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—Except as provided in paragraph (2), in the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, part 7 of subtitle B of title I of Employee Retirement Income Security Act of 1974 (other than section 701(e) thereof) shall not apply to plan years beginning before the later of—

(A) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act), or

(B) July 1, 1997.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement of such part shall not be treated as a termination of such collective bargaining agreement.

(4) TIMELY REGULATIONS.—The Secretary of Labor, consistent with section 104, shall first issue by not later than April 1, 1997, such regulations as may be necessary to carry out the amendments made by this section.

(5) LIMITATION ON ACTIONS.—No enforcement action shall be taken, pursuant to the amendments made by this section, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by such amendments before January 1, 1998, or, if later, the date of issuance of regulations referred to in paragraph (4), if the plan or issuer has sought to comply in good faith with such requirements.

SEC. 102. THROUGH THE PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—The Public Health Service Act is amended by adding at the end the following new title:

<< 42 USCA Ch. 6A >>

“TITLE XXVII—ASSURING PORTABILITY, AVAILABILITY,
AND RENEWABILITY OF HEALTH INSURANCE COVERAGE

“PART A—GROUP MARKET REFORMS

“Subpart 1—Portability, Access, and Renewability Requirements

<< 42 USCA § 300gg >>

“SEC. 2701. INCREASED PORTABILITY THROUGH LIMITATION ON PREEXISTING CONDITION EXCLUSIONS.

“(a) LIMITATION ON PREEXISTING CONDITION EXCLUSION PERIOD; CREDITING FOR PERIODS OF PREVIOUS COVERAGE.—Subject to subsection (d), a group health plan, and a health insurance issuer offering group health insurance coverage, may, with respect to a participant or beneficiary, impose a preexisting condition exclusion only if—

“(1) such exclusion relates to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6-month period ending on the enrollment date;

“(2) such exclusion extends for a period of not more than 12 months (or 18 months in the case of a late enrollee) after the enrollment date; and

“(3) the period of any such preexisting condition exclusion is reduced by the aggregate of the periods of creditable coverage (if any, as defined in subsection (c)(1)) applicable to the participant or beneficiary as of the enrollment date.

“(b) DEFINITIONS.—For purposes of this part—

“(1) PREEXISTING CONDITION EXCLUSION.—

“(A) IN GENERAL.—The term ‘preexisting condition exclusion’ means, with respect to coverage, a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.

“(B) TREATMENT OF GENETIC INFORMATION.—Genetic information shall not be treated as a condition described in subsection (a)(1) in the absence of a diagnosis of the condition related to such information.

“(2) ENROLLMENT DATE.—The term ‘enrollment date’ means, with respect to an individual covered under a group health plan or health insurance coverage, the date of enrollment of the individual in the plan or coverage or, if earlier, the first day of the waiting period for such enrollment.

“(3) LATE ENROLLEE.—The term ‘late enrollee’ means, with respect to coverage under a group health plan, a participant or beneficiary who enrolls under the plan other than during—

“(A) the first period in which the individual is eligible to enroll under the plan, or

“(B) a special enrollment period under subsection (f).

“(4) WAITING PERIOD.—The term ‘waiting period’ means, with respect to a group health plan and an individual who is a potential participant or beneficiary in the plan, the period that must pass with respect to the individual before the individual is eligible to be covered for benefits under the terms of the plan.

“(c) RULES RELATING TO CREDITING PREVIOUS COVERAGE.—

“(1) CREDITABLE COVERAGE DEFINED.—For purposes of this title, the term ‘creditable coverage’ means, with respect to an individual, coverage of the individual under any of the following:

“(A) A group health plan.

“(B) Health insurance coverage.

“(C) Part A or part B of title XVIII of the Social Security Act.

“(D) Title XIX of the Social Security Act, other than coverage consisting solely of benefits under section 1928.

“(E) Chapter 55 of title 10, United States Code.

“(F) A medical care program of the Indian Health Service or of a tribal organization.

“(G) A State health benefits risk pool.

“(H) A health plan offered under chapter 89 of title 5, United States Code.

“(I) A public health plan (as defined in regulations).

“(J) A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

Such term does not include coverage consisting solely of coverage of excepted benefits (as defined in section 2791(c)).

“(2) NOT COUNTING PERIODS BEFORE SIGNIFICANT BREAKS IN COVERAGE.—

“(A) IN GENERAL.—A period of creditable coverage shall not be counted, with respect to enrollment of an individual under a group health plan, if, after such period and before the enrollment date, there was a 63-day period during all of which the individual was not covered under any creditable coverage.

“(B) WAITING PERIOD NOT TREATED AS A BREAK IN COVERAGE.—For purposes of subparagraph (A) and subsection (d)(4), any period that an individual is in a waiting period for any coverage under a group health plan (or for group health insurance coverage) or is in an affiliation period (as defined in subsection (g)(2)) shall not be taken into account in determining the continuous period under subparagraph (A).

“(3) METHOD OF CREDITING COVERAGE.—

“(A) STANDARD METHOD.—Except as otherwise provided under subparagraph (B), for purposes of applying subsection (a)(3), a group health plan, and a health insurance issuer offering group health insurance coverage, shall count a period of creditable coverage without regard to the specific benefits covered during the period.

“(B) ELECTION OF ALTERNATIVE METHOD.—A group health plan, or a health insurance issuer offering group health insurance, may elect to apply subsection (a)(3) based on coverage of benefits within each of several classes or categories of benefits specified in regulations rather than as provided under subparagraph (A). Such election shall be made on a uniform

basis for all participants and beneficiaries. Under such election a group health plan or issuer shall count a period of creditable coverage with respect to any class or category of benefits if any level of benefits is covered within such class or category.

“(C) PLAN NOTICE.—In the case of an election with respect to a group health plan under subparagraph (B) (whether or not health insurance coverage is provided in connection with such plan), the plan shall—

“(i) prominently state in any disclosure statements concerning the plan, and state to each enrollee at the time of enrollment under the plan, that the plan has made such election, and

“(ii) include in such statements a description of the effect of this election.

“(D) ISSUER NOTICE.—In the case of an election under subparagraph (B) with respect to health insurance coverage offered by an issuer in the small or large group market, the issuer—

“(i) shall prominently state in any disclosure statements concerning the coverage, and to each employer at the time of the offer or sale of the coverage, that the issuer has made such election, and

“(ii) shall include in such statements a description of the effect of such election.

“(4) ESTABLISHMENT OF PERIOD.—Periods of creditable coverage with respect to an individual shall be established through presentation of certifications described in subsection (e) or in such other manner as may be specified in regulations.

“(d) EXCEPTIONS.—

“(1) EXCLUSION NOT APPLICABLE TO CERTAIN NEWBORNS.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion in the case of an individual who, as of the last day of the 30-day period beginning with the date of birth, is covered under creditable coverage.

“(2) EXCLUSION NOT APPLICABLE TO CERTAIN ADOPTED CHILDREN.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion in the case of a child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30-day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. The previous sentence shall not apply to coverage before the date of such adoption or placement for adoption.

“(3) EXCLUSION NOT APPLICABLE TO PREGNANCY.—A group health plan, and health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion relating to pregnancy as a preexisting condition.

“(4) LOSS IF BREAK IN COVERAGE.—Paragraphs (1) and (2) shall no longer apply to an individual after the end of the first 63-day period during all of which the individual was not covered under any creditable coverage.

“(e) CERTIFICATIONS AND DISCLOSURE OF COVERAGE.—

“(1) REQUIREMENT FOR CERTIFICATION OF PERIOD OF CREDITABLE COVERAGE.—

“(A) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide the certification described in subparagraph (B)—

“(i) at the time an individual ceases to be covered under the plan or otherwise becomes covered under a COBRA continuation provision,

“(ii) in the case of an individual becoming covered under such a provision, at the time the individual ceases to be covered under such provision, and

“(iii) on the request on behalf of an individual made not later than 24 months after the date of cessation of the coverage described in clause (i) or (ii), whichever is later.

The certification under clause (i) may be provided, to the extent practicable, at a time consistent with notices required under any applicable COBRA continuation provision.

“(B) CERTIFICATION.—The certification described in this subparagraph is a written certification of—

“(i) the period of creditable coverage of the individual under such plan and the coverage (if any) under such COBRA continuation provision, and

“(ii) the waiting period (if any) (and affiliation period, if applicable) imposed with respect to the individual for any coverage under such plan.

“(C) ISSUER COMPLIANCE.—To the extent that medical care under a group health plan consists of group health insurance coverage, the plan is deemed to have satisfied the certification requirement under this paragraph if the health insurance issuer offering the coverage provides for such certification in accordance with this paragraph.

“(2) DISCLOSURE OF INFORMATION ON PREVIOUS BENEFITS.—In the case of an election described in subsection (c)(3)(B) by a group health plan or health insurance issuer, if the plan or issuer enrolls an individual for coverage under the plan and the individual provides a certification of coverage of the individual under paragraph (1)—

“(A) upon request of such plan or issuer, the entity which issued the certification provided by the individual shall promptly disclose to such requesting plan or issuer information on coverage of classes and categories of health benefits available under such entity's plan or coverage, and

“(B) such entity may charge the requesting plan or issuer for the reasonable cost of disclosing such information.

“(3) REGULATIONS.—The Secretary shall establish rules to prevent an entity's failure to provide information under paragraph (1) or (2) with respect to previous coverage of an individual from adversely affecting any subsequent coverage of the individual under another group health plan or health insurance coverage.

“(f) SPECIAL ENROLLMENT PERIODS.—

“(1) INDIVIDUALS LOSING OTHER COVERAGE.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if each of the following conditions is met:

“(A) The employee or dependent was covered under a group health plan or had health insurance coverage at the time coverage was previously offered to the employee or dependent.

“(B) The employee stated in writing at such time that coverage under a group health plan or health insurance coverage was the reason for declining enrollment, but only if the plan sponsor or issuer (if applicable) required such a statement at such time and provided the employee with notice of such requirement (and the consequences of such requirement) at such time.

“(C) The employee's or dependent's coverage described in subparagraph (A)—

“(i) was under a COBRA continuation provision and the coverage under such provision was exhausted; or

“(ii) was not under such a provision and either the coverage was terminated as a result of loss of eligibility for the coverage (including as a result of legal separation, divorce, death, termination of employment, or reduction in the number of hours of employment) or employer contributions toward such coverage were terminated.

“(D) Under the terms of the plan, the employee requests such enrollment not later than 30 days after the date of exhaustion of coverage described in subparagraph (C)(i) or termination of coverage or employer contribution described in subparagraph (C)(ii).

“(2) FOR DEPENDENT BENEFICIARIES.—

“(A) IN GENERAL.—If—

“(i) a group health plan makes coverage available with respect to a dependent of an individual,

“(ii) the individual is a participant under the plan (or has met any waiting period applicable to becoming a participant under the plan and is eligible to be enrolled under the plan but for a failure to enroll during a previous enrollment period), and

“(iii) a person becomes such a dependent of the individual through marriage, birth, or adoption or placement for adoption,

the group health plan shall provide for a dependent special enrollment period described in subparagraph (B) during which the person (or, if not otherwise enrolled, the individual) may be enrolled under the plan as a dependent of the individual, and in the case of the birth or adoption of a child, the spouse of the individual may be enrolled as a dependent of the individual if such spouse is otherwise eligible for coverage.

“(B) DEPENDENT SPECIAL ENROLLMENT PERIOD.—A dependent special enrollment period under this subparagraph shall be a period of not less than 30 days and shall begin on the later of—

“(i) the date dependent coverage is made available, or

“(ii) the date of the marriage, birth, or adoption or placement for adoption (as the case may be) described in subparagraph (A)(iii).

“(C) NO WAITING PERIOD.—If an individual seeks to enroll a dependent during the first 30 days of such a dependent special enrollment period, the coverage of the dependent shall become effective—

“(i) in the case of marriage, not later than the first day of the first month beginning after the date the completed request for enrollment is received;

“(ii) in the case of a dependent's birth, as of the date of such birth; or

“(iii) in the case of a dependent's adoption or placement for adoption, the date of such adoption or placement for adoption.

“(g) USE OF AFFILIATION PERIOD BY HMOS AS ALTERNATIVE TO PREEXISTING CONDITION EXCLUSION.—

“(1) IN GENERAL.—A health maintenance organization which offers health insurance coverage in connection with a group health plan and which does not impose any preexisting condition exclusion allowed under subsection (a) with respect to any particular coverage option may impose an affiliation period for such coverage option, but only if—

“(A) such period is applied uniformly without regard to any health status-related factors; and

“(B) such period does not exceed 2 months (or 3 months in the case of a late enrollee).

“(2) AFFILIATION PERIOD.—

“(A) DEFINED.—For purposes of this title, the term ‘affiliation period’ means a period which, under the terms of the health insurance coverage offered by the health maintenance organization, must expire before the health insurance coverage becomes effective. The organization is not required to provide health care services or benefits during such period and no premium shall be charged to the participant or beneficiary for any coverage during the period.

“(B) BEGINNING.—Such period shall begin on the enrollment date.

“(C) RUNS CONCURRENTLY WITH WAITING PERIODS.—An affiliation period under a plan shall run concurrently with any waiting period under the plan.

“(3) ALTERNATIVE METHODS.—A health maintenance organization described in paragraph (1) may use alternative methods, from those described in such paragraph, to address adverse selection as approved by the State insurance commissioner or official or officials designated by the State to enforce the requirements of this part for the State involved with respect to such issuer.

<< 42 USCA § 300gg-1 >>

“SEC. 2702. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

“(a) IN ELIGIBILITY TO ENROLL.—

“(1) IN GENERAL.—Subject to paragraph (2), a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

“(A) Health status.

“(B) Medical condition (including both physical and mental illnesses).

“(C) Claims experience.

“(D) Receipt of health care.

“(E) Medical history.

“(F) Genetic information.

“(G) Evidence of insurability (including conditions arising out of acts of domestic violence).

“(H) Disability.

“(2) NO APPLICATION TO BENEFITS OR EXCLUSIONS.—To the extent consistent with section 701, paragraph (1) shall not be construed—

“(A) to require a group health plan, or group health insurance coverage, to provide particular benefits other than those provided under the terms of such plan or coverage, or

“(B) to prevent such a plan or coverage from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

“(3) CONSTRUCTION.—For purposes of paragraph (1), rules for eligibility to enroll under a plan include rules defining any applicable waiting periods for such enrollment.

“(b) IN PREMIUM CONTRIBUTIONS.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled

in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

“(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

“(A) to restrict the amount that an employer may be charged for coverage under a group health plan; or

“(B) to prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

<< 42 USCA Ch. 6A >>

“Subpart 2—Provisions Applicable Only to Health Insurance Issuers

<< 42 USCA § 300gg-11 >>

“SEC. 2711. GUARANTEED AVAILABILITY OF COVERAGE FOR EMPLOYERS IN THE GROUP MARKET.

“(a) ISSUANCE OF COVERAGE IN THE SMALL GROUP MARKET.—

“(1) IN GENERAL.—Subject to subsections (c) through (f), each health insurance issuer that offers health insurance coverage in the small group market in a State—

“(A) must accept every small employer (as defined in section 2791(e)(4)) in the State that applies for such coverage; and

“(B) must accept for enrollment under such coverage every eligible individual (as defined in paragraph (2)) who applies for enrollment during the period in which the individual first becomes eligible to enroll under the terms of the group health plan and may not place any restriction which is inconsistent with section 2702 on an eligible individual being a participant or beneficiary.

“(2) ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this section, the term ‘eligible individual’ means, with respect to a health insurance issuer that offers health insurance coverage to a small employer in connection with a group health plan in the small group market, such an individual in relation to the employer as shall be determined—

“(A) in accordance with the terms of such plan,

“(B) as provided by the issuer under rules of the issuer which are uniformly applicable in a State to small employers in the small group market, and

“(C) in accordance with all applicable State laws governing such issuer and such market.

“(b) ASSURING ACCESS IN THE LARGE GROUP MARKET.—

“(1) REPORTS TO HHS.—The Secretary shall request that the chief executive officer of each State submit to the Secretary, by not later December 31, 2000, and every 3 years thereafter a report on—

“(A) the access of large employers to health insurance coverage in the State, and

“(B) the circumstances for lack of access (if any) of large employers (or one or more classes of such employers) in the State to such coverage.

“(2) TRIENNIAL REPORTS TO CONGRESS.—The Secretary, based on the reports submitted under paragraph (1) and such other information as the Secretary may use, shall prepare and submit to Congress, every 3 years, a report describing the extent to which large employers (and classes of such employers) that seek health insurance coverage in the different States are able to obtain access to such coverage. Such report shall include such recommendations as the Secretary determines to be appropriate.

“(3) GAO REPORT ON LARGE EMPLOYER ACCESS TO HEALTH INSURANCE COVERAGE.—The Comptroller General shall provide for a study of the extent to which classes of large employers in the different States are able to obtain access to health insurance coverage and the circumstances for lack of access (if any) to such coverage. The Comptroller General shall submit to Congress a report on such study not later than 18 months after the date of the enactment of this title.

“(c) SPECIAL RULES FOR NETWORK PLANS.—

“(1) IN GENERAL.—In the case of a health insurance issuer that offers health insurance coverage in the small group market through a network plan, the issuer may—

“(A) limit the employers that may apply for such coverage to those with eligible individuals who live, work, or reside in the service area for such network plan; and

“(B) within the service area of such plan, deny such coverage to such employers if the issuer has demonstrated, if required, to the applicable State authority that—

“(i) it will not have the capacity to deliver services adequately to enrollees of any additional groups because of its obligations to existing group contract holders and enrollees, and

“(ii) it is applying this paragraph uniformly to all employers without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to such employees and dependents.

“(2) 180-DAY SUSPENSION UPON DENIAL OF COVERAGE.—An issuer, upon denying health insurance coverage in any service area in accordance with paragraph (1)(B), may not offer coverage in the small group market within such service area for a period of 180 days after the date such coverage is denied.

“(d) APPLICATION OF FINANCIAL CAPACITY LIMITS.—

“(1) IN GENERAL.—A health insurance issuer may deny health insurance coverage in the small group market if the issuer has demonstrated, if required, to the applicable State authority that—

“(A) it does not have the financial reserves necessary to underwrite additional coverage; and

“(B) it is applying this paragraph uniformly to all employers in the small group market in the State consistent with applicable State law and without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to such employees and dependents.

“(2) 180-DAY SUSPENSION UPON DENIAL OF COVERAGE.—A health insurance issuer upon denying health insurance coverage in connection with group health plans in accordance with paragraph (1) in a State may not offer coverage in connection with group health plans in the small group market in the State for a period of 180 days after the date such coverage is denied or until the issuer has demonstrated to the applicable State authority, if required under applicable State law, that the issuer has sufficient financial reserves to underwrite additional coverage, whichever is later. An applicable State authority may provide for the application of this subsection on a service-area-specific basis.

“(e) EXCEPTION TO REQUIREMENT FOR FAILURE TO MEET CERTAIN MINIMUM PARTICIPATION OR CONTRIBUTION RULES.—

“(1) IN GENERAL.—Subsection (a) shall not be construed to preclude a health insurance issuer from establishing employer contribution rules or group participation rules for the offering of health insurance coverage in connection with a group health plan in the small group market, as allowed under applicable State law.

“(2) RULES DEFINED.—For purposes of paragraph (1)—

“(A) the term ‘employer contribution rule’ means a requirement relating to the minimum level or amount of employer contribution toward the premium for enrollment of participants and beneficiaries; and

“(B) the term ‘group participation rule’ means a requirement relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer.

“(f) EXCEPTION FOR COVERAGE OFFERED ONLY TO BONA FIDE ASSOCIATION MEMBERS.—Subsection (a) shall not apply to health insurance coverage offered by a health insurance issuer if such coverage is made available in the small group market only through one or more bona fide associations (as defined in section 2791(d)(3)).

<< 42 USCA § 300gg-12 >>

“SEC. 2712. GUARANTEED RENEWABILITY OF COVERAGE FOR EMPLOYERS IN THE GROUP MARKET.

“(a) IN GENERAL.—Except as provided in this section, if a health insurance issuer offers health insurance coverage in the small or large group market in connection with a group health plan, the issuer must renew or continue in force such coverage at the option of the plan sponsor of the plan.

“(b) GENERAL EXCEPTIONS.—A health insurance issuer may nonrenew or discontinue health insurance coverage offered in connection with a group health plan in the small or large group market based only on one or more of the following:

“(1) NONPAYMENT OF PREMIUMS.—The plan sponsor has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage or the issuer has not received timely premium payments.

“(2) FRAUD.—The plan sponsor has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage.

“(3) VIOLATION OF PARTICIPATION OR CONTRIBUTION RULES.—The plan sponsor has failed to comply with a material plan provision relating to employer contribution or group participation rules, as permitted under section 2711(e) in the case of the small group market or pursuant to applicable State law in the case of the large group market.

“(4) TERMINATION OF COVERAGE.—The issuer is ceasing to offer coverage in such market in accordance with subsection (c) and applicable State law.

“(5) MOVEMENT OUTSIDE SERVICE AREA.—In the case of a health insurance issuer that offers health insurance coverage in the market through a network plan, there is no longer any enrollee in connection with such plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business) and, in the case of the small group market, the issuer would deny enrollment with respect to such plan under section 2711(c)(1)(A).

“(6) ASSOCIATION MEMBERSHIP CEASES.—In the case of health insurance coverage that is made available in the small or large group market (as the case may be) only through one or more bona fide associations, the membership of an employer in the association (on the basis of which the coverage is provided) ceases but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor relating to any covered individual.

“(c) REQUIREMENTS FOR UNIFORM TERMINATION OF COVERAGE.—

“(1) PARTICULAR TYPE OF COVERAGE NOT OFFERED.—In any case in which an issuer decides to discontinue offering a particular type of group health insurance coverage offered in the small or large group market, coverage of such type may be discontinued by the issuer in accordance with applicable State law in such market only if—

“(A) the issuer provides notice to each plan sponsor provided coverage of this type in such market (and participants and beneficiaries covered under such coverage) of such discontinuation at least 90 days prior to the date of the discontinuation of such coverage;

“(B) the issuer offers to each plan sponsor provided coverage of this type in such market, the option to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan in such market; and

“(C) in exercising the option to discontinue coverage of this type and in offering the option of coverage under subparagraph (B), the issuer acts uniformly without regard to the claims experience of those sponsors or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

“(2) DISCONTINUANCE OF ALL COVERAGE.—

“(A) IN GENERAL.—In any case in which a health insurance issuer elects to discontinue offering all health insurance coverage in the small group market or the large group market, or both markets, in a State, health insurance coverage may be discontinued by the issuer only in accordance with applicable State law and if—

“(i) the issuer provides notice to the applicable State authority and to each plan sponsor (and participants and beneficiaries covered under such coverage) of such discontinuation at least 180 days prior to the date of the discontinuation of such coverage; and

“(ii) all health insurance issued or delivered for issuance in the State in such market (or markets) are discontinued and coverage under such health insurance coverage in such market (or markets) is not renewed.

“(B) PROHIBITION ON MARKET REENTRY.—In the case of a discontinuation under subparagraph (A) in a market, the issuer may not provide for the issuance of any health insurance coverage in the market and State involved during the 5-year period beginning on the date of the discontinuation of the last health insurance coverage not so renewed.

“(d) EXCEPTION FOR UNIFORM MODIFICATION OF COVERAGE.—At the time of coverage renewal, a health insurance issuer may modify the health insurance coverage for a product offered to a group health plan—

“(1) in the large group market; or

“(2) in the small group market if, for coverage that is available in such market other than only through one or more bona fide associations, such modification is consistent with State law and effective on a uniform basis among group health plans with that product.

“(e) APPLICATION TO COVERAGE OFFERED ONLY THROUGH ASSOCIATIONS.—In applying this section in the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, a reference to ‘plan sponsor’ is deemed, with respect to coverage provided to an employer member of the association, to include a reference to such employer.

<< 42 USCA § 300gg-13 >>

“SEC. 2713. DISCLOSURE OF INFORMATION.

“(a) DISCLOSURE OF INFORMATION BY HEALTH PLAN ISSUERS.—In connection with the offering of any health insurance coverage to a small employer, a health insurance issuer—

“(1) shall make a reasonable disclosure to such employer, as part of its solicitation and sales materials, of the availability of information described in subsection (b), and

“(2) upon request of such a small employer, provide such information.

“(b) INFORMATION DESCRIBED.—

“(1) IN GENERAL.—Subject to paragraph (3), with respect to a health insurance issuer offering health insurance coverage to a small employer, information described in this subsection is information concerning—

“(A) the provisions of such coverage concerning issuer's right to change premium rates and the factors that may affect changes in premium rates;

“(B) the provisions of such coverage relating to renewability of coverage;

“(C) the provisions of such coverage relating to any preexisting condition exclusion; and

“(D) the benefits and premiums available under all health insurance coverage for which the employer is qualified.

“(2) FORM OF INFORMATION.—Information under this subsection shall be provided to small employers in a manner determined to be understandable by the average small employer, and shall be sufficient to reasonably inform small employers of their rights and obligations under the health insurance coverage.

“(3) EXCEPTION.—An issuer is not required under this section to disclose any information that is proprietary and trade secret information under applicable law.

<< 42 USCA Ch. 6A >>

“Subpart 3—Exclusion of Plans; Enforcement; Preemption

<< 42 USCA § 300gg-21 >>

“SEC. 2721. EXCLUSION OF CERTAIN PLANS.

“(a) EXCEPTION FOR CERTAIN SMALL GROUP HEALTH PLANS.—The requirements of subparts 1 and 2 shall not apply to any group health plan (and health insurance coverage offered in connection with a group health plan) for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees.

“(b) LIMITATION ON APPLICATION OF PROVISIONS RELATING TO GROUP HEALTH PLANS.—

“(1) IN GENERAL.—The requirements of subparts 1 and 2 shall apply with respect to group health plans only—

“(A) subject to paragraph (2), in the case of a plan that is a nonfederal governmental plan, and

“(B) with respect to health insurance coverage offered in connection with a group health plan (including such a plan that is a church plan or a governmental plan).

“(2) TREATMENT OF NONFEDERAL GOVERNMENTAL PLANS.—

“(A) ELECTION TO BE EXCLUDED.—If the plan sponsor of a nonfederal governmental plan which is a group health plan to which the provisions of subparts 1 and 2 otherwise apply makes an election under this subparagraph (in such form and manner as the Secretary may by regulations prescribe), then the requirements of such subparts insofar as they apply directly to group health plans (and not merely to group health insurance coverage) shall not apply to such governmental plans for such period except as provided in this paragraph.

“(B) PERIOD OF ELECTION.—An election under subparagraph (A) shall apply—

“(i) for a single specified plan year, or

“(ii) in the case of a plan provided pursuant to a collective bargaining agreement, for the term of such agreement.

An election under clause (i) may be extended through subsequent elections under this paragraph.

“(C) NOTICE TO ENROLLEES.—Under such an election, the plan shall provide for—

“(i) notice to enrollees (on an annual basis and at the time of enrollment under the plan) of the fact and consequences of such election, and

“(ii) certification and disclosure of creditable coverage under the plan with respect to enrollees in accordance with section 2701(e).

“(c) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of subparts 1 and 2 shall not apply to any group health plan (or group health insurance coverage) in relation to its provision of excepted benefits described in section 2791(c)(1).

“(d) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—

“(1) LIMITED, EXCEPTED BENEFITS.—The requirements of subparts 1 and 2 shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 2791(c)(2) if the benefits—

“(A) are provided under a separate policy, certificate, or contract of insurance; or

“(B) are otherwise not an integral part of the plan.

“(2) NONCOORDINATED, EXCEPTED BENEFITS.—The requirements of subparts 1 and 2 shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 2791(c)(3) if all of the following conditions are met:

“(A) The benefits are provided under a separate policy, certificate, or contract of insurance.

“(B) There is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor.

“(C) Such benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor.

“(3) SUPPLEMENTAL EXCEPTED BENEFITS.—The requirements of this part shall not apply to any group health plan (and group health insurance coverage) in relation to its provision of excepted benefits described in section 2791(c)(4) if the benefits are provided under a separate policy, certificate, or contract of insurance.

“(e) TREATMENT OF PARTNERSHIPS.—For purposes of this part—

“(1) TREATMENT AS A GROUP HEALTH PLAN.—Any plan, fund, or program which would not be (but for this subsection) an employee welfare benefit plan and which is established or maintained by a partnership, to the extent that such plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, shall be treated (subject to paragraph (2)) as an employee welfare benefit plan which is a group health plan.

“(2) EMPLOYER.—In the case of a group health plan, the term ‘employer’ also includes the partnership in relation to any partner.

“(3) PARTICIPANTS OF GROUP HEALTH PLANS.—In the case of a group health plan, the term ‘participant’ also includes —

“(A) in connection with a group health plan maintained by a partnership, an individual who is a partner in relation to the partnership, or

“(B) in connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the self-employed individual,

if such individual is, or may become, eligible to receive a benefit under the plan or such individual's beneficiaries may be eligible to receive any such benefit.

<< 42 USCA § 300gg-22 >>

“SEC. 2722. ENFORCEMENT.

“(a) STATE ENFORCEMENT.—

“(1) STATE AUTHORITY.—Subject to section 2723, each State may require that health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State in the small or large group markets meet the requirements of this part with respect to such issuers.

“(2) FAILURE TO IMPLEMENT PROVISIONS.—In the case of a determination by the Secretary that a State has failed to substantially enforce a provision (or provisions) in this part with respect to health insurance issuers in the State, the Secretary shall enforce such provision (or provisions) under subsection (b) insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in connection with group health plans in such State.

“(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

“(1) LIMITATION.—The provisions of this subsection shall apply to enforcement of a provision (or provisions) of this part only—

“(A) as provided under subsection (a)(2); and

“(B) with respect to group health plans that are non-Federal governmental plans.

“(2) IMPOSITION OF PENALTIES.—In the cases described in paragraph (1)—

“(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, any non-Federal governmental plan that is a group health plan and any health insurance issuer that fails to meet a provision of this part applicable to such plan or issuer is subject to a civil money penalty under this subsection.

“(B) LIABILITY FOR PENALTY.—In the case of a failure by—

“(i) a health insurance issuer, the issuer is liable for such penalty, or

“(ii) a group health plan that is a non-Federal governmental plan which is—

“(I) sponsored by 2 or more employers, the plan is liable for such penalty, or

“(II) not so sponsored, the employer is liable for such penalty.

“(C) AMOUNT OF PENALTY.—

“(i) IN GENERAL.—The maximum amount of penalty imposed under this paragraph is \$100 for each day for each individual with respect to which such a failure occurs.

“(ii) CONSIDERATIONS IN IMPOSITION.—In determining the amount of any penalty to be assessed under this paragraph, the Secretary shall take into account the previous record of compliance of the entity being assessed with the applicable provisions of this part and the gravity of the violation.

“(iii) LIMITATIONS.—

“(I) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No civil money penalty shall be imposed under this paragraph on any failure during any period for which it is established to the satisfaction of the Secretary that none of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

“(II) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN 30 DAYS.—No civil money penalty shall be imposed under this paragraph on any failure if such failure was due to reasonable cause and not to willful neglect, and such failure is corrected during the 30-day period beginning on the first day any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

“(D) ADMINISTRATIVE REVIEW.—

“(i) OPPORTUNITY FOR HEARING.—The entity assessed shall be afforded an opportunity for hearing by the Secretary upon request made within 30 days after the date of the issuance of a notice of assessment. In such hearing the decision shall be made on the record pursuant to section 554 of title 5, United States Code. If no hearing is requested, the assessment shall constitute a final and unappealable order.

“(ii) HEARING PROCEDURE.—If a hearing is requested, the initial agency decision shall be made by an administrative law judge, and such decision shall become the final order unless the Secretary modifies or vacates the decision. Notice of intent to modify or vacate the decision of the administrative law judge shall be issued to the parties within 30 days after the date of the decision of the judge. A final order which takes effect under this paragraph shall be subject to review only as provided under subparagraph (E).

“(E) JUDICIAL REVIEW.—

“(i) FILING OF ACTION FOR REVIEW.—Any entity against whom an order imposing a civil money penalty has been entered after an agency hearing under this paragraph may obtain review by the United States district court for any district in which such entity is located or the United States District Court for the District of Columbia by filing a notice of appeal in such court within 30 days from the date of such order, and simultaneously sending a copy of such notice by registered mail to the Secretary.

“(ii) CERTIFICATION OF ADMINISTRATIVE RECORD.—The Secretary shall promptly certify and file in such court the record upon which the penalty was imposed.

“(iii) STANDARD FOR REVIEW.—The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence as provided by section 706(2)(E) of title 5, United States Code.

“(iv) APPEAL.—Any final decision, order, or judgment of the district court concerning such review shall be subject to appeal as provided in chapter 83 of title 28 of such Code.

“(F) FAILURE TO PAY ASSESSMENT; MAINTENANCE OF ACTION.—

“(i) FAILURE TO PAY ASSESSMENT.—If any entity fails to pay an assessment after it has become a final and unappealable order, or after the court has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General who shall recover the amount assessed by action in the appropriate United States district court.

“(ii) NONREVIEWABILITY.—In such action the validity and appropriateness of the final order imposing the penalty shall not be subject to review.

“(G) PAYMENT OF PENALTIES.—Except as otherwise provided, penalties collected under this paragraph shall be paid to the Secretary (or other officer) imposing the penalty and shall be available without appropriation and until expended for the purpose of enforcing the provisions with respect to which the penalty was imposed.

<< 42 USCA § 300gg-23 >>

“SEC. 2723. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

“(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

“(1) IN GENERAL.—Subject to paragraph (2) and except as provided in subsection (b), this part and part C insofar as it relates to this part shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part.

“(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this part shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 with respect to group health plans.

“(b) SPECIAL RULES IN CASE OF PORTABILITY REQUIREMENTS.—

“(1) IN GENERAL.—Subject to paragraph (2), the provisions of this part relating to health insurance coverage offered by a health insurance issuer supersede any provision of State law which establishes, implements, or continues in effect a standard or requirement applicable to imposition of a preexisting condition exclusion specifically governed by section 701 which differs from the standards or requirements specified in such section.

“(2) EXCEPTIONS.—Only in relation to health insurance coverage offered by a health insurance issuer, the provisions of this part do not supersede any provision of State law to the extent that such provision—

“(i) substitutes for the reference to ‘6-month period’ in section 2701(a)(1) a reference to any shorter period of time;

“(ii) substitutes for the reference to ‘12 months’ and ‘18 months’ in section 2701(a)(2) a reference to any shorter period of time;

“(iii) substitutes for the references to ‘63’ days in sections 2701(c)(2)(A) and 2701(d)(4)(A) a reference to any greater number of days;

“(iv) substitutes for the reference to ‘30-day period’ in sections 2701(b)(2) and 2701(d)(1) a reference to any greater period;

“(v) prohibits the imposition of any preexisting condition exclusion in cases not described in section 2701(d) or expands the exceptions described in such section;

“(vi) requires special enrollment periods in addition to those required under section 2701(f); or

“(vii) reduces the maximum period permitted in an affiliation period under section 2701(g)(1)(B).

“(c) RULES OF CONSTRUCTION.—Nothing in this part shall be construed as requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

“(d) DEFINITIONS.—For purposes of this section—

“(1) STATE LAW.—The term ‘State law’ includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

“(2) STATE.—The term ‘State’ includes a State (including the Northern Mariana Islands), any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

<< 42 USCA Ch. 6A >>

“PART C—DEFINITIONS; MISCELLANEOUS PROVISIONS

<< 42 USCA § 300gg–91 >>

“SEC. 2791. DEFINITIONS.

“(a) GROUP HEALTH PLAN.—

“(1) DEFINITION.—The term ‘group health plan’ means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974) to the extent that the plan provides medical care (as defined in paragraph (2)) and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

“(2) MEDICAL CARE.—The term ‘medical care’ means amounts paid for—

“(A) the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body,

“(B) amounts paid for transportation primarily for and essential to medical care referred to in subparagraph (A), and

“(C) amounts paid for insurance covering medical care referred to in subparagraphs (A) and (B).

“(3) TREATMENT OF CERTAIN PLANS AS GROUP HEALTH PLAN FOR NOTICE PROVISION.—A program under which creditable coverage described in subparagraph (C), (D), (E), or (F) of section 2701(c)(1) is provided shall be treated as a group health plan for purposes of applying section 2701(e).

“(b) DEFINITIONS RELATING TO HEALTH INSURANCE.—

“(1) HEALTH INSURANCE COVERAGE.—The term ‘health insurance coverage’ means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as medical care) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer.

“(2) HEALTH INSURANCE ISSUER.—The term ‘health insurance issuer’ means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in paragraph (3)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974). Such term does not include a group health plan.

“(3) HEALTH MAINTENANCE ORGANIZATION.—The term ‘health maintenance organization’ means—

“(A) a Federally qualified health maintenance organization (as defined in section 1301(a)),

“(B) an organization recognized under State law as a health maintenance organization, or

“(C) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

“(4) GROUP HEALTH INSURANCE COVERAGE.—The term ‘group health insurance coverage’ means, in connection with a group health plan, health insurance coverage offered in connection with such plan.

“(5) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The term ‘individual health insurance coverage’ means health insurance coverage offered to individuals in the individual market, but does not include short-term limited duration insurance.

“(c) EXCEPTED BENEFITS.—For purposes of this title, the term ‘excepted benefits’ means benefits under one or more (or any combination thereof) of the following:

“(1) BENEFITS NOT SUBJECT TO REQUIREMENTS.—

“(A) Coverage only for accident, or disability income insurance, or any combination thereof.

“(B) Coverage issued as a supplement to liability insurance.

“(C) Liability insurance, including general liability insurance and automobile liability insurance.

“(D) Workers' compensation or similar insurance.

“(E) Automobile medical payment insurance.

“(F) Credit-only insurance.

“(G) Coverage for on-site medical clinics.

“(H) Other similar insurance coverage, specified in regulations, under which benefits for medical care are secondary or incidental to other insurance benefits.

“(2) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED SEPARATELY.—

“(A) Limited scope dental or vision benefits.

“(B) Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof.

“(C) Such other similar, limited benefits as are specified in regulations.

“(3) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS INDEPENDENT, NONCOORDINATED BENEFITS.—

“(A) Coverage only for a specified disease or illness.

“(B) Hospital indemnity or other fixed indemnity insurance.

“(4) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS SEPARATE INSURANCE POLICY.—Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act), coverage supplemental to the coverage provided under chapter 55 of title 10, United States Code, and similar supplemental coverage provided to coverage under a group health plan.

“(d) OTHER DEFINITIONS.—

“(1) APPLICABLE STATE AUTHORITY.—The term ‘applicable State authority’ means, with respect to a health insurance issuer in a State, the State insurance commissioner or official or officials designated by the State to enforce the requirements of this title for the State involved with respect to such issuer.

“(2) BENEFICIARY.—The term ‘beneficiary’ has the meaning given such term under section 3(8) of the Employee Retirement Income Security Act of 1974.

“(3) BONA FIDE ASSOCIATION.—The term ‘bona fide association’ means, with respect to health insurance coverage offered in a State, an association which—

“(A) has been actively in existence for at least 5 years;

“(B) has been formed and maintained in good faith for purposes other than obtaining insurance;

“(C) does not condition membership in the association on any health status-related factor relating to an individual (including an employee of an employer or a dependent of an employee);

“(D) makes health insurance coverage offered through the association available to all members regardless of any health status-related factor relating to such members (or individuals eligible for coverage through a member);

“(E) does not make health insurance coverage offered through the association available other than in connection with a member of the association; and

“(F) meets such additional requirements as may be imposed under State law.

“(4) COBRA CONTINUATION PROVISION.—The term ‘COBRA continuation provision’ means any of the following:

“(A) Section 4980B of the Internal Revenue Code of 1986, other than subsection (f)(1) of such section insofar as it relates to pediatric vaccines.

“(B) Part 6 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, other than section 609 of such Act.

“(C) Title XXII of this Act.

“(5) EMPLOYEE.—The term ‘employee’ has the meaning given such term under section 3(6) of the Employee Retirement Income Security Act of 1974.

“(6) EMPLOYER.—The term ‘employer’ has the meaning given such term under section 3(5) of the Employee Retirement Income Security Act of 1974, except that such term shall include only employers of two or more employees.

“(7) CHURCH PLAN.—The term ‘church plan’ has the meaning given such term under section 3(33) of the Employee Retirement Income Security Act of 1974.

“(8) GOVERNMENTAL PLAN.—(A) The term ‘governmental plan’ has the meaning given such term under section 3(32) of the Employee Retirement Income Security Act of 1974 and any Federal governmental plan.

“(B) FEDERAL GOVERNMENTAL PLAN.—The term ‘Federal governmental plan’ means a governmental plan established or maintained for its employees by the Government of the United States or by any agency or instrumentality of such Government.

“(C) NON-FEDERAL GOVERNMENTAL PLAN.—The term ‘non-Federal governmental plan’ means a governmental plan that is not a Federal governmental plan.

“(9) HEALTH STATUS-RELATED FACTOR.—The term ‘health status-related factor’ means any of the factors described in section 2702(a)(1).

“(10) NETWORK PLAN.—The term ‘network plan’ means health insurance coverage of a health insurance issuer under which the financing and delivery of medical care (including items and services paid for as medical care) are provided, in whole or in part, through a defined set of providers under contract with the issuer.

“(11) PARTICIPANT.—The term ‘participant’ has the meaning given such term under section 3(7) of the Employee Retirement Income Security Act of 1974.

“(12) PLACED FOR ADOPTION DEFINED.—The term ‘placement’, or being ‘placed’, for adoption, in connection with any placement for adoption of a child with any person, means the assumption and retention by such person of a legal obligation for total or partial support of such child in anticipation of adoption of such child. The child's placement with such person terminates upon the termination of such legal obligation.

“(13) PLAN SPONSOR.—The term ‘plan sponsor’ has the meaning given such term under section 3(16)(B) of the Employee Retirement Income Security Act of 1974.

“(14) STATE.—The term ‘State’ means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

“(e) DEFINITIONS RELATING TO MARKETS AND SMALL EMPLOYERS.—For purposes of this title:

“(1) INDIVIDUAL MARKET.—

“(A) IN GENERAL.—The term ‘individual market’ means the market for health insurance coverage offered to individuals other than in connection with a group health plan.

“(B) TREATMENT OF VERY SMALL GROUPS.—

“(i) IN GENERAL.—Subject to clause (ii), such terms includes coverage offered in connection with a group health plan that has fewer than two participants as current employees on the first day of the plan year.

“(ii) STATE EXCEPTION.—Clause (i) shall not apply in the case of a State that elects to regulate the coverage described in such clause as coverage in the small group market.

“(2) LARGE EMPLOYER.—The term ‘large employer’ means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year.

“(3) LARGE GROUP MARKET.—The term ‘large group market’ means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a large employer.

“(4) SMALL EMPLOYER.—The term ‘small employer’ means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year.

“(5) SMALL GROUP MARKET.—The term ‘small group market’ means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a small employer.

“(6) APPLICATION OF CERTAIN RULES IN DETERMINATION OF EMPLOYER SIZE.—For purposes of this subsection—

“(A) APPLICATION OF AGGREGATION RULE FOR EMPLOYERS.—all persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 of the Internal Revenue Code of 1986 shall be treated as 1 employer.

“(B) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence throughout the preceding calendar year, the determination of whether such employer is a small or large employer shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

“(C) PREDECESSORS.—Any reference in this subsection to an employer shall include a reference to any predecessor of such employer.

<< 42 USCA § 300gg–92 >>

“SEC. 2792. REGULATIONS.

“The Secretary, consistent with section 104 of the Health Care Portability and Accountability Act of 1996, may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this title. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this title.”.

<< 42 USCA § 300e >>

(b) APPLICATION OF RULES BY CERTAIN HEALTH MAINTENANCE ORGANIZATIONS.—Section 1301 of such Act (42 U.S.C. 300e) is amended by adding at the end the following new subsection:

“(d) An organization that offers health benefits coverage shall not be considered as failing to meet the requirements of this section notwithstanding that it provides, with respect to coverage offered in connection with a group health plan in the small or large group market (as defined in section 2791(e)), an affiliation period consistent with the provisions of section 2701(g).”.

<< 42 USCA §§ 300gg NOTE, 300gg–1 nt, 300gg–11 nt, 300gg–12 nt, 300gg–
13 nt, 300gg–21 nt, 300gg–22 nt, 300gg–23 nt, 300gg–91 nt, 300gg–92 nt >>

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, part A of title XXVII of the Public Health Service Act (as added by subsection (a)) shall apply with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after June 30, 1997.

(2) DETERMINATION OF CREDITABLE COVERAGE.—

(A) PERIOD OF COVERAGE.—

(i) IN GENERAL.—Subject to clause (ii), no period before July 1, 1996, shall be taken into account under part A of title XXVII of the Public Health Service Act (as added by this section) in determining creditable coverage.

(ii) SPECIAL RULE FOR CERTAIN PERIODS.—The Secretary of Health and Human Services, consistent with section 104, shall provide for a process whereby individuals who need to establish creditable coverage for periods before July 1, 1996, and who would have such coverage credited but for clause (i) may be given credit for creditable coverage for such periods through the presentation of documents or other means.

(B) CERTIFICATIONS, ETC.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), subsection (e) of section 2701 of the Public Health Service Act (as added by this section) shall apply to events occurring after June 30, 1996.

(ii) NO CERTIFICATION REQUIRED TO BE PROVIDED BEFORE JUNE 1, 1997.—In no case is a certification required to be provided under such subsection before June 1, 1997.

(iii) CERTIFICATION ONLY ON WRITTEN REQUEST FOR EVENTS OCCURRING BEFORE OCTOBER 1, 1996.—In the case of an event occurring after June 30, 1996, and before October 1, 1996, a certification is not required to be provided under such subsection unless an individual (with respect to whom the certification is otherwise required to be made) requests such certification in writing.

(C) TRANSITIONAL RULE.—In the case of an individual who seeks to establish creditable coverage for any period for which certification is not required because it relates to an event occurring before June 30, 1996—

(i) the individual may present other credible evidence of such coverage in order to establish the period of creditable coverage; and

(ii) a group health plan and a health insurance issuer shall not be subject to any penalty or enforcement action with respect to the plan's or issuer's crediting (or not crediting) such coverage if the plan or issuer has sought to comply in good faith with the applicable requirements under the amendments made by this section.

(3) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—Except as provided in paragraph (2)(B), in the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, part A of title XXVII of the Public Health Service Act (other than section 2701(e) thereof) shall not apply to plan years beginning before the later of—

(A) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act), or

(B) July 1, 1997.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement of such part shall not be treated as a termination of such collective bargaining agreement.

(4) TIMELY REGULATIONS.—The Secretary of Health and Human Services, consistent with section 104, shall first issue by not later than April 1, 1997, such regulations as may be necessary to carry out the amendments made by this section and section 111.

(5) LIMITATION ON ACTIONS.—No enforcement action shall be taken, pursuant to the amendments made by this section, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by such amendments before January 1, 1998, or, if later, the date of issuance of regulations referred to in paragraph (4), if the plan or issuer has sought to comply in good faith with such requirements.

<< 42 USCA § 300bb-8 >>

(d) MISCELLANEOUS CORRECTION.—Section 2208(1) of the Public Health Service Act (42 U.S.C. 300bb-8(1)) is amended by striking “section 162(i)(2)” and inserting “5000(b)”.

SEC. 103. REFERENCE TO IMPLEMENTATION THROUGH THE INTERNAL REVENUE CODE OF 1986.

For provisions amending the Internal Revenue Code of 1986 to provide for application and enforcement of rules for group health plans similar to those provided under the amendments made by section 101(a), see section 401.

<< 42 USCA § 300gg-92 NOTE >>

SEC. 104. ASSURING COORDINATION.

The Secretary of the Treasury, the Secretary of Health and Human Services, and the Secretary of Labor shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which two or more such Secretaries have responsibility under this subtitle (and the amendments made by this subtitle and section 401) are administered so as to have the same effect at all times; and

(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

Subtitle B—Individual Market Rules

SEC. 111. AMENDMENT TO PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Title XXVII of the Public Health Service Act, as added by section 102(a) of this Act, is amended by inserting after part A the following new part:

<< 42 USCA Ch. 6A >>

“PART B—INDIVIDUAL MARKET RULES

<< 42 USCA § 300gg-41 >>

“SEC. 2741. GUARANTEED AVAILABILITY OF INDIVIDUAL HEALTH INSURANCE COVERAGE TO CERTAIN INDIVIDUALS WITH PRIOR GROUP COVERAGE.

“(a) GUARANTEED AVAILABILITY.—

“(1) IN GENERAL.—Subject to the succeeding subsections of this section and section 2744, each health insurance issuer that offers health insurance coverage (as defined in section 2791(b)(1)) in the individual market in a State may not, with respect to an eligible individual (as defined in subsection (b)) desiring to enroll in individual health insurance coverage—

“(A) decline to offer such coverage to, or deny enrollment of, such individual; or

“(B) impose any preexisting condition exclusion (as defined in section 2701(b)(1)(A)) with respect to such coverage.

“(2) SUBSTITUTION BY STATE OF ACCEPTABLE ALTERNATIVE MECHANISM.—The requirement of paragraph (1) shall not apply to health insurance coverage offered in the individual market in a State in which the State is implementing an acceptable alternative mechanism under section 2744.

“(b) ELIGIBLE INDIVIDUAL DEFINED.—In this part, the term ‘eligible individual’ means an individual—

“(1)(A) for whom, as of the date on which the individual seeks coverage under this section, the aggregate of the periods of creditable coverage (as defined in section 2701(c)) is 18 or more months and (B) whose most recent prior creditable coverage was under a group health plan, governmental plan, or church plan (or health insurance coverage offered in connection with any such plan);

“(2) who is not eligible for coverage under (A) a group health plan, (B) part A or part B of title XVIII of the Social Security Act, or (C) a State plan under title XIX of such Act (or any successor program), and does not have other health insurance coverage;

“(3) with respect to whom the most recent coverage within the coverage period described in paragraph (1)(A) was not terminated based on a factor described in paragraph (1) or (2) of section 2712(b) (relating to nonpayment of premiums or fraud);

“(4) if the individual had been offered the option of continuation coverage under a COBRA continuation provision or under a similar State program, who elected such coverage; and

“(5) who, if the individual elected such continuation coverage, has exhausted such continuation coverage under such provision or program.

“(c) ALTERNATIVE COVERAGE PERMITTED WHERE NO STATE MECHANISM.—

“(1) IN GENERAL.—In the case of health insurance coverage offered in the individual market in a State in which the State is not implementing an acceptable alternative mechanism under section 2744, the health insurance issuer may elect to limit the coverage offered under subsection (a) so long as it offers at least two different policy forms of health insurance coverage both of which—

“(A) are designed for, made generally available to, and actively marketed to, and enroll both eligible and other individuals by the issuer; and

“(B) meet the requirement of paragraph (2) or (3), as elected by the issuer.

For purposes of this subsection, policy forms which have different cost-sharing arrangements or different riders shall be considered to be different policy forms.

“(2) CHOICE OF MOST POPULAR POLICY FORMS.—The requirement of this paragraph is met, for health insurance coverage policy forms offered by an issuer in the individual market, if the issuer offers the policy forms for individual health insurance coverage with the largest, and next to largest, premium volume of all such policy forms offered by the issuer in the State or applicable marketing or service area (as may be prescribed in regulation) by the issuer in the individual market in the period involved.

“(3) CHOICE OF 2 POLICY FORMS WITH REPRESENTATIVE COVERAGE.—

“(A) IN GENERAL.—The requirement of this paragraph is met, for health insurance coverage policy forms offered by an issuer in the individual market, if the issuer offers a lower-level coverage policy form (as defined in subparagraph (B)) and a higher-level coverage policy form (as defined in subparagraph (C)) each of which includes benefits substantially similar to other individual health insurance coverage offered by the issuer in that State and each of which is covered under a method described in section 2744(c)(3)(A) (relating to risk adjustment, risk spreading, or financial subsidization).

“(B) LOWER-LEVEL OF COVERAGE DESCRIBED.—A policy form is described in this subparagraph if the actuarial value of the benefits under the coverage is at least 85 percent but not greater than 100 percent of a weighted average (described in subparagraph (D)).

“(C) HIGHER-LEVEL OF COVERAGE DESCRIBED.—A policy form is described in this subparagraph if—

“(i) the actuarial value of the benefits under the coverage is at least 15 percent greater than the actuarial value of the coverage described in subparagraph (B) offered by the issuer in the area involved; and

“(ii) the actuarial value of the benefits under the coverage is at least 100 percent but not greater than 120 percent of a weighted average (described in subparagraph (D)).

“(D) WEIGHTED AVERAGE.—For purposes of this paragraph, the weighted average described in this subparagraph is the average actuarial value of the benefits provided by all the health insurance coverage issued (as elected by the issuer) either by that issuer or by all issuers in the State in the individual market during the previous year (not including coverage issued under this section), weighted by enrollment for the different coverage.

“(4) ELECTION.—The issuer elections under this subsection shall apply uniformly to all eligible individuals in the State for that issuer. Such an election shall be effective for policies offered during a period of not shorter than 2 years.

“(5) ASSUMPTIONS.—For purposes of paragraph (3), the actuarial value of benefits provided under individual health insurance coverage shall be calculated based on a standardized population and a set of standardized utilization and cost factors.

“(d) SPECIAL RULES FOR NETWORK PLANS.—

“(1) IN GENERAL.—In the case of a health insurance issuer that offers health insurance coverage in the individual market through a network plan, the issuer may—

“(A) limit the individuals who may be enrolled under such coverage to those who live, reside, or work within the service area for such network plan; and

“(B) within the service area of such plan, deny such coverage to such individuals if the issuer has demonstrated, if required, to the applicable State authority that—

“(i) it will not have the capacity to deliver services adequately to additional individual enrollees because of its obligations to existing group contract holders and enrollees and individual enrollees, and

“(ii) it is applying this paragraph uniformly to individuals without regard to any health status-related factor of such individuals and without regard to whether the individuals are eligible individuals.

“(2) 180-DAY SUSPENSION UPON DENIAL OF COVERAGE.—An issuer, upon denying health insurance coverage in any service area in accordance with paragraph (1)(B), may not offer coverage in the individual market within such service area for a period of 180 days after such coverage is denied.

“(e) APPLICATION OF FINANCIAL CAPACITY LIMITS.—

“(1) IN GENERAL.—A health insurance issuer may deny health insurance coverage in the individual market to an eligible individual if the issuer has demonstrated, if required, to the applicable State authority that—

“(A) it does not have the financial reserves necessary to underwrite additional coverage; and

“(B) it is applying this paragraph uniformly to all individuals in the individual market in the State consistent with applicable State law and without regard to any health status-related factor of such individuals and without regard to whether the individuals are eligible individuals.

“(2) 180-DAY SUSPENSION UPON DENIAL OF COVERAGE.—An issuer upon denying individual health insurance coverage in any service area in accordance with paragraph (1) may not offer such coverage in the individual market within such service area for a period of 180 days after the date such coverage is denied or until the issuer has demonstrated, if required under applicable State law, to the applicable State authority that the issuer has sufficient financial reserves to underwrite additional coverage, whichever is later. A State may provide for the application of this paragraph on a service-area-specific basis.

“(e) MARKET REQUIREMENTS.—

“(1) IN GENERAL.—The provisions of subsection (a) shall not be construed to require that a health insurance issuer offering health insurance coverage only in connection with group health plans or through one or more bona fide associations, or both, offer such health insurance coverage in the individual market.

“(2) CONVERSION POLICIES.—A health insurance issuer offering health insurance coverage in connection with group health plans under this title shall not be deemed to be a health insurance issuer offering individual health insurance coverage solely because such issuer offers a conversion policy.

“(f) CONSTRUCTION.—Nothing in this section shall be construed—

“(1) to restrict the amount of the premium rates that an issuer may charge an individual for health insurance coverage provided in the individual market under applicable State law; or

“(2) to prevent a health insurance issuer offering health insurance coverage in the individual market from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

<< 42 USCA § 300gg-42 >>

“SEC. 2742. GUARANTEED RENEWABILITY OF INDIVIDUAL HEALTH INSURANCE COVERAGE.

“(a) IN GENERAL.—Except as provided in this section, a health insurance issuer that provides individual health insurance coverage to an individual shall renew or continue in force such coverage at the option of the individual.

“(b) GENERAL EXCEPTIONS.—A health insurance issuer may nonrenew or discontinue health insurance coverage of an individual in the individual market based only on one or more of the following:

“(1) NONPAYMENT OF PREMIUMS.—The individual has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage or the issuer has not received timely premium payments.

“(2) FRAUD.—The individual has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage.

“(3) TERMINATION OF PLAN.—The issuer is ceasing to offer coverage in the individual market in accordance with subsection (c) and applicable State law.

“(4) MOVEMENT OUTSIDE SERVICE AREA.—In the case of a health insurance issuer that offers health insurance coverage in the market through a network plan, the individual no longer resides, lives, or works in the service area (or in an area for which the issuer is authorized to do business) but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor of covered individuals.

“(5) ASSOCIATION MEMBERSHIP CEASES.—In the case of health insurance coverage that is made available in the individual market only through one or more bona fide associations, the membership of the individual in the association (on the basis of which the coverage is provided) ceases but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor of covered individuals.

“(c) REQUIREMENTS FOR UNIFORM TERMINATION OF COVERAGE.—

“(1) PARTICULAR TYPE OF COVERAGE NOT OFFERED.—In any case in which an issuer decides to discontinue offering a particular type of health insurance coverage offered in the individual market, coverage of such type may be discontinued by the issuer only if—

“(A) the issuer provides notice to each covered individual provided coverage of this type in such market of such discontinuation at least 90 days prior to the date of the discontinuation of such coverage;

“(B) the issuer offers to each individual in the individual market provided coverage of this type, the option to purchase any other individual health insurance coverage currently being offered by the issuer for individuals in such market; and

“(C) in exercising the option to discontinue coverage of this type and in offering the option of coverage under subparagraph (B), the issuer acts uniformly without regard to any health status-related factor of enrolled individuals or individuals who may become eligible for such coverage.

“(2) DISCONTINUANCE OF ALL COVERAGE.—

“(A) IN GENERAL.—Subject to subparagraph (C), in any case in which a health insurance issuer elects to discontinue offering all health insurance coverage in the individual market in a State, health insurance coverage may be discontinued by the issuer only if—

“(i) the issuer provides notice to the applicable State authority and to each individual of such discontinuation at least 180 days prior to the date of the expiration of such coverage, and

“(ii) all health insurance issued or delivered for issuance in the State in such market are discontinued and coverage under such health insurance coverage in such market is not renewed.

“(B) PROHIBITION ON MARKET REENTRY.—In the case of a discontinuation under subparagraph (A) in the individual market, the issuer may not provide for the issuance of any health insurance coverage in the market and State involved during the 5-year period beginning on the date of the discontinuation of the last health insurance coverage not so renewed.

“(d) EXCEPTION FOR UNIFORM MODIFICATION OF COVERAGE.—At the time of coverage renewal, a health insurance issuer may modify the health insurance coverage for a policy form offered to individuals in the individual market so long as such modification is consistent with State law and effective on a uniform basis among all individuals with that policy form.

“(e) APPLICATION TO COVERAGE OFFERED ONLY THROUGH ASSOCIATIONS.—In applying this section in the case of health insurance coverage that is made available by a health insurance issuer in the individual market to individuals only through one or more associations, a reference to an ‘individual’ is deemed to include a reference to such an association (of which the individual is a member).

<< 42 USCA § 300gg-43 >>

“SEC. 2743. CERTIFICATION OF COVERAGE.

“The provisions of section 2701(e) shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as it applies to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

<< 42 USCA § 300gg-44 >>

“SEC. 2744. STATE FLEXIBILITY IN INDIVIDUAL MARKET REFORMS.

“(a) WAIVER OF REQUIREMENTS WHERE IMPLEMENTATION OF ACCEPTABLE ALTERNATIVE MECHANISM.

—
“(1) IN GENERAL.—The requirements of section 2741 shall not apply with respect to health insurance coverage offered in the individual market in the State so long as a State is found to be implementing, in accordance with this section and consistent with section 2746(b), an alternative mechanism (in this section referred to as an ‘acceptable alternative mechanism’)—

“(A) under which all eligible individuals are provided a choice of health insurance coverage;

“(B) under which such coverage does not impose any preexisting condition exclusion with respect to such coverage;

“(C) under which such choice of coverage includes at least one policy form of coverage that is comparable to comprehensive health insurance coverage offered in the individual market in such State or that is comparable to a standard option of coverage available under the group or individual health insurance laws of such State; and

“(D) in a State which is implementing—

“(i) a model act described in subsection (c)(1),

“(ii) a qualified high risk pool described in subsection (c)(2), or

“(iii) a mechanism described in subsection (c)(3).

“(2) PERMISSIBLE FORMS OF MECHANISMS.—A private or public individual health insurance mechanism (such as a health insurance coverage pool or programs, mandatory group conversion policies, guaranteed issue of one or more plans of individual health insurance coverage, or open enrollment by one or more health insurance issuers), or combination of such mechanisms, that is designed to provide access to health benefits for individuals in the individual market in the State in accordance with this section may constitute an acceptable alternative mechanism.

“(b) APPLICATION OF ACCEPTABLE ALTERNATIVE MECHANISMS.—

“(1) PRESUMPTION.—

“(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, a State is presumed to be implementing an acceptable alternative mechanism in accordance with this section as of July 1, 1997, if, by not later than April 1, 1997, the chief executive officer of a State—

“(i) notifies the Secretary that the State has enacted or intends to enact (by not later than January 1, 1998, or July 1, 1998, in the case of a State described in subparagraph (B)(ii)) any necessary legislation to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism as of January 1, 1998, (or, in the case of a State described in subparagraph (B)(ii), July 1, 1998); and

“(ii) provides the Secretary with such information as the Secretary may require to review the mechanism and its implementation (or proposed implementation) under this subsection.

“(B) DELAY PERMITTED FOR CERTAIN STATES.—

“(i) EFFECT OF DELAY.—In the case of a State described in clause (ii) that provides notice under subparagraph (A)(i), for the presumption to continue on and after July 1, 1998, the chief executive officer of the State by April 1, 1998—

“(I) must notify the Secretary that the State has enacted any necessary legislation to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism as of July 1, 1998; and

“(II) must provide the Secretary with such information as the Secretary may require to review the mechanism and its implementation (or proposed implementation) under this subsection.

“(ii) STATES DESCRIBED.—A State described in this clause is a State that has a legislature that does not meet within the 12-month period beginning on the date of enactment of this Act.

“(C) CONTINUED APPLICATION.—In order for a mechanism to continue to be presumed to be an acceptable alternative mechanism, the State shall provide the Secretary every 3 years with information described in subparagraph (A)(ii) or (B)(i) (II) (as the case may be).

“(2) NOTICE.—If the Secretary finds, after review of information provided under paragraph (1) and in consultation with the chief executive officer of the State and the insurance commissioner or chief insurance regulatory official of the State, that such a mechanism is not an acceptable alternative mechanism or is not (or no longer) being implemented, the Secretary—

“(A) shall notify the State of—

“(i) such preliminary determination, and

“(ii) the consequences under paragraph (3) of a failure to implement such a mechanism; and

“(B) shall permit the State a reasonable opportunity in which to modify the mechanism (or to adopt another mechanism) in a manner so that may be an acceptable alternative mechanism or to provide for implementation of such a mechanism.

“(3) FINAL DETERMINATION.—If, after providing notice and opportunity under paragraph (2), the Secretary finds that the mechanism is not an acceptable alternative mechanism or the State is not implementing such a mechanism, the Secretary shall notify the State that the State is no longer considered to be implementing an acceptable alternative mechanism and that the requirements of section 2741 shall apply to health insurance coverage offered in the individual market in the State, effective as of a date specified in the notice.

“(4) LIMITATION ON SECRETARIAL AUTHORITY.—The Secretary shall not make a determination under paragraph (2) or (3) on any basis other than the basis that a mechanism is not an acceptable alternative mechanism or is not being implemented.

“(5) FUTURE ADOPTION OF MECHANISMS.—If a State, after January 1, 1997, submits the notice and information described in paragraph (1), unless the Secretary makes a finding described in paragraph (3) within the 90-day period beginning on the date of submission of the notice and information, the mechanism shall be considered to be an acceptable alternative mechanism for purposes of this section, effective 90 days after the end of such period, subject to the second sentence of paragraph (1).

“(c) PROVISION RELATED TO RISK.—

“(1) ADOPTION OF NAIC MODELS.—The model act referred to in subsection (a)(1)(D)(i) is the Small Employer and Individual Health Insurance Availability Model Act (adopted by the National Association of Insurance Commissioners on June 3, 1996) insofar as it applies to individual health insurance coverage or the Individual Health Insurance Portability Model Act (also adopted by such Association on such date).

“(2) QUALIFIED HIGH RISK POOL.—For purposes of subsection (a)(1)(D)(ii), a ‘qualified high risk pool’ described in this paragraph is a high risk pool that—

“(A) provides to all eligible individuals health insurance coverage (or comparable coverage) that does not impose any preexisting condition exclusion with respect to such coverage for all eligible individuals, and

“(B) provides for premium rates and covered benefits for such coverage consistent with standards included in the NAIC Model Health Plan for Uninsurable Individuals Act (as in effect as of the date of the enactment of this title).

“(3) OTHER MECHANISMS.—For purposes of subsection (a)(1)(D)(iii), a mechanism described in this paragraph—

“(A) provides for risk adjustment, risk spreading, or a risk spreading mechanism (among issuers or policies of an issuer) or otherwise provides for some financial subsidization for eligible individuals, including through assistance to participating issuers; or

“(B) is a mechanism under which each eligible individual is provided a choice of all individual health insurance coverage otherwise available.

<< 42 USCA § 300gg-45 >>

“SEC. 2745. ENFORCEMENT.

“(a) STATE ENFORCEMENT.—

“(1) STATE AUTHORITY.—Subject to section 2746, each State may require that health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State in the individual market meet the requirements established under this part with respect to such issuers.

“(2) FAILURE TO IMPLEMENT REQUIREMENTS.—In the case of a State that fails to substantially enforce the requirements set forth in this part with respect to health insurance issuers in the State, the Secretary shall enforce the requirements of this part under subsection (b) insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in the individual market in such State.

“(b) SECRETARIAL ENFORCEMENT AUTHORITY.—The Secretary shall have the same authority in relation to enforcement of the provisions of this part with respect to issuers of health insurance coverage in the individual market in a State as the Secretary has under section 2722(b)(2) in relation to the enforcement of the provisions of part A with respect to issuers of health insurance coverage in the small group market in the State.

<< 42 USCA § 300gg-46 >>

“SEC. 2746. PREEMPTION.

“(a) IN GENERAL.—Subject to subsection (b), nothing in this part (or part C insofar as it applies to this part) shall be construed to prevent a State from establishing, implementing, or continuing in effect standards and requirements unless such standards and requirements prevent the application of a requirement of this part.

“(b) RULES OF CONSTRUCTION.—Nothing in this part (or part C insofar as it applies to this part) shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144).

<< 42 USCA § 300gg-47 >>

“SEC. 2747. GENERAL EXCEPTIONS.

“(a) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of this part shall not apply to any health insurance coverage in relation to its provision of excepted benefits described in section 2791(c)(1).

“(b) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—The requirements of this part shall not apply to any health insurance coverage in relation to its provision of excepted benefits described in paragraph (2), (3), or (4) of section 2791(c) if the benefits are provided under a separate policy, certificate, or contract of insurance.”.

<< 42 USCA §§ 300gg-41 NOTE, 300gg-42 nt, 300gg-43 nt, 300gg-44 nt, 300gg-45 nt, 300gg-46 nt, 300gg-47 nt >>

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, part B of title XXVII of the Public Health Service Act (as inserted by subsection (a)) shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs.

(2) APPLICATION OF CERTIFICATION RULES.—The provisions of section 102(d)(2) of this Act shall apply to section 2743 of the Public Health Service Act in the same manner as it applies to section 2701(e) of such Act.

Subtitle C—General and Miscellaneous Provisions

<< 42 USCA § 300gg NOTE >>

SEC. 191. HEALTH COVERAGE AVAILABILITY STUDIES.

(a) STUDIES.—

(1) STUDY ON EFFECTIVENESS OF REFORMS.—The Secretary of Health and Human Services shall provide for a study on the effectiveness of the provisions of this title and the various State laws, in ensuring the availability of reasonably priced health coverage to employers purchasing group coverage and individuals purchasing coverage on a non-group basis.

(2) STUDY ON ACCESS AND CHOICE.—The Secretary also shall provide for a study on—

(A) the extent to which patients have direct access to, and choice of, health care providers, including specialty providers, within a network plan, as well as the opportunity to utilize providers outside of the network plan, under the various types of coverage offered under the provisions of this title; and

(B) the cost and cost-effectiveness to health insurance issuers of providing access to out-of-network providers, and the potential impact of providing such access on the cost and quality of health insurance coverage offered under provisions of this title.

(3) CONSULTATION.—The studies under this subsection shall be conducted in consultation with the Secretary of Labor, representatives of State officials, consumers, and other representatives of individuals and entities that have expertise in health insurance and employee benefits.

(b) REPORTS.—Not later than January 1, 2000, the Secretary shall submit to the appropriate committees of Congress a report on each of the studies under subsection (a).

SEC. 192. REPORT ON MEDICARE REIMBURSEMENT OF TELEMEDICINE.

The Health Care Financing Administration shall complete its ongoing study of Medicare reimbursement of all telemedicine services and submit a report to Congress on Medicare reimbursement of telemedicine services by not later than March 1, 1997. The report shall—

(1) utilize data compiled from the current demonstration projects already under review and gather data from other ongoing telemedicine networks;

(2) include an analysis of the cost of services provided via telemedicine; and

(3) include a proposal for Medicare reimbursement of such services.

<< 42 USCA § 300e >>

SEC. 193. ALLOWING FEDERALLY-QUALIFIED HMOS TO OFFER HIGH DEDUCTIBLE PLANS.

Section 1301(b) of the Public Health Service Act (42 U.S.C. 300e(b)) is amended by adding at the end the following new paragraph:

“(6) A health maintenance organization that otherwise meets the requirements of this title may offer a high-deductible health plan (as defined in section 220(c)(2) of the Internal Revenue Code of 1986).”.

<< 42 USCA § 233 >>

SEC. 194. VOLUNTEER SERVICES PROVIDED BY HEALTH PROFESSIONALS AT FREE CLINICS.

Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended by adding at the end the following subsection:

“(o)(1) For purposes of this section, a free clinic health professional shall in providing a qualifying health service to an individual be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (6)(D). The preceding sentence is subject to the provisions of this subsection.

“(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a free clinic health professional if the following conditions are met:

“(A) The service is provided to the individual at a free clinic, or through offsite programs or events carried out by the free clinic.

“(B) The free clinic is sponsoring the health care practitioner pursuant to paragraph (5)(C).

“(C) The service is a qualifying health service (as defined in paragraph (4)).

“(D) Neither the health care practitioner nor the free clinic receives any compensation for the service from the individual or from any third-party payor (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program). With respect to compliance with such condition:

“(i) The health care practitioner may receive repayment from the free clinic for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual.

“(ii) The free clinic may accept voluntary donations for the provision of the service by the health care practitioner to the individual.

“(E) Before the service is provided, the health care practitioner or the free clinic provides written notice to the individual of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection (or in the case of an emergency, the written notice is provided to the individual as soon after the emergency as is practicable). If the individual is a minor or is otherwise legally incompetent, the condition under this subparagraph is that the written notice be provided to a legal guardian or other person with legal responsibility for the care of the individual.

“(F) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable law regarding the provision of the service.

“(3)(A) For purposes of this subsection, the term ‘free clinic’ means a health care facility operated by a nonprofit private entity meeting the following requirements:

“(i) The entity does not, in providing health services through the facility, accept reimbursement from any third-party payor (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program).

“(ii) The entity, in providing health services through the facility, either does not impose charges on the individuals to whom the services are provided, or imposes a charge according to the ability of the individual involved to pay the charge.

“(iii) The entity is licensed or certified in accordance with applicable law regarding the provision of health services.

“(B) With respect to compliance with the conditions under subparagraph (A), the entity involved may accept voluntary donations for the provision of services.

“(4) For purposes of this subsection, the term ‘qualifying health service’ means any medical assistance required or authorized to be provided in the program under title XIX of the Social Security Act, without regard to whether the medical assistance is included in the plan submitted under such program by the State in which the health care practitioner involved provides the medical assistance. References in the preceding sentence to such program shall as applicable be considered to be references to any successor to such program.

“(5) Subsection (g) (other than paragraphs (3) through (5)) and subsections (h), (i), and (l) apply to a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or contractor of an entity described in subsection (g)(4), subject to paragraph (6) and subject to the following:

“(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

“(B) This subsection may not be construed as deeming any free clinic to be an employee of the Public Health Service for purposes of this section.

“(C) With respect to a free clinic, a health care practitioner is not a free clinic health professional unless the free clinic sponsors the health care practitioner. For purposes of this subsection, the free clinic shall be considered to be sponsoring the health care practitioner if—

“(i) with respect to the health care practitioner, the free clinic submits to the Secretary an application meeting the requirements of subsection (g)(1)(D); and

“(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

“(D) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a free clinic health professional, this subsection applies to the health care practitioner (with respect to the free clinic sponsoring the health care practitioner pursuant to subparagraph (C)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

“(E) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

“(6)(A) For purposes of making payments for judgments against the United States (together with related fees and expenses of witnesses) pursuant to this section arising from the acts or omissions of free clinic health professionals, there is authorized to be appropriated \$10,000,000 for each fiscal year.

“(B) The Secretary shall establish a fund for purposes of this subsection. Each fiscal year amounts appropriated under subparagraph (A) shall be deposited in such fund.

“(C) Not later than May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of free clinic health professionals, will be paid pursuant to this section during the calendar year that begins in the following fiscal year. Subsection (k)(1)(B) applies to the estimate under the preceding sentence regarding free clinic health professionals to the same extent and in the same manner as such subsection applies to the estimate under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

“(D) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subparagraph (B) to the appropriate accounts in the Treasury an amount equal to the estimate made under subparagraph (C) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

“(7)(A) This subsection takes effect on the date of the enactment of the first appropriations Act that makes an appropriation under paragraph (6)(A), except as provided in subparagraph (B)(i).

“(B)(i) Effective on the date of the enactment of the Health Insurance Portability and Accountability Act of 1996—

“(I) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (5)(C); and

“(II) reports under paragraph (6)(C) may be submitted to the Congress.

“(ii) For the first fiscal year for which an appropriation is made under subparagraph (A) of paragraph (6), if an estimate under subparagraph (C) of such paragraph has not been made for the calendar year beginning in such fiscal year, the transfer under subparagraph (D) of such paragraph shall be made notwithstanding the lack of the estimate, and the transfer shall be made in an amount equal to the amount of such appropriation.”.

<< 42 USCA § 300gg NOTE >>

SEC. 195. FINDINGS; SEVERABILITY.

(a) FINDINGS RELATING TO EXERCISE OF COMMERCE CLAUSE AUTHORITY.—Congress finds the following in relation to the provisions of this title:

(1) Provisions in group health plans and health insurance coverage that impose certain preexisting condition exclusions impact the ability of employees to seek employment in interstate commerce, thereby impeding such commerce.

(2) Health insurance coverage is commercial in nature and is in and affects interstate commerce.

(3) It is a necessary and proper exercise of Congressional authority to impose requirements under this title on group health plans and health insurance coverage (including coverage offered to individuals previously covered under group health plans) in order to promote commerce among the States.

(4) Congress, however, intends to defer to States, to the maximum extent practicable, in carrying out such requirements with respect to insurers and health maintenance organizations that are subject to State regulation, consistent with the provisions of the Employee Retirement Income Security Act of 1974.

<< 29 USCA §§ 1003 nt, 1021 nt, 1022 nt, 1024 nt, 1132 nt, 1136 nt,
1144 nt, 1181 nt, 1182 nt, 1183 nt, 1184 nt, 1185 nt, 1186 nt, 1187 nt >>

<< 42 USCA §§ 233 nt, 300e nt, 300bb–8 nt, 300gg–1 nt, 300gg–11 nt, 300gg–12 nt,
300gg–13 nt, 300gg–21 nt, 300gg–22 nt, 300gg–23 nt, 300gg–41 nt, 300gg–42 nt, 300gg–
43 nt, 300gg–44 nt, 300gg–45 nt, 300gg–46 nt, 300gg–47 nt, 300gg–91 nt, 300gg–92 nt >>

(b) SEVERABILITY.—If any provision of this title or the application of such provision to any person or circumstance is held to be unconstitutional, the remainder of this title and the application of the provisions of such to any person or circumstance shall not be affected thereby.

TITLE II—PREVENTING HEALTH CARE FRAUD AND ABUSE; ADMINISTRATIVE SIMPLIFICATION

SEC. 200. REFERENCES IN TITLE.

Except as otherwise specifically provided, whenever in this title an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

Subtitle A—Fraud and Abuse Control Program

SEC. 201. FRAUD AND ABUSE CONTROL PROGRAM.

<< 42 USCA § 1320a-7c >>

(a) ESTABLISHMENT OF PROGRAM.—Title XI (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128B the following new section:

“FRAUD AND ABUSE CONTROL PROGRAM

“SEC. 1128C. (a) ESTABLISHMENT OF PROGRAM.—

“(1) IN GENERAL.—Not later than January 1, 1997, the Secretary, acting through the Office of the Inspector General of the Department of Health and Human Services, and the Attorney General shall establish a program—

“(A) to coordinate Federal, State, and local law enforcement programs to control fraud and abuse with respect to health plans,

“(B) to conduct investigations, audits, evaluations, and inspections relating to the delivery of and payment for health care in the United States,

“(C) to facilitate the enforcement of the provisions of sections 1128, 1128A, and 1128B and other statutes applicable to health care fraud and abuse,

“(D) to provide for the modification and establishment of safe harbors and to issue advisory opinions and special fraud alerts pursuant to section 1128D, and

“(E) to provide for the reporting and disclosure of certain final adverse actions against health care providers, suppliers, or practitioners pursuant to the data collection system established under section 1128E.

“(2) COORDINATION WITH HEALTH PLANS.—In carrying out the program established under paragraph (1), the Secretary and the Attorney General shall consult with, and arrange for the sharing of data with representatives of health plans.

“(3) GUIDELINES.—

“(A) IN GENERAL.—The Secretary and the Attorney General shall issue guidelines to carry out the program under paragraph (1). The provisions of sections 553, 556, and 557 of title 5, United States Code, shall not apply in the issuance of such guidelines.

“(B) INFORMATION GUIDELINES.—

“(i) IN GENERAL.—Such guidelines shall include guidelines relating to the furnishing of information by health plans, providers, and others to enable the Secretary and the Attorney General to carry out the program (including coordination with health plans under paragraph (2)).

“(ii) CONFIDENTIALITY.—Such guidelines shall include procedures to assure that such information is provided and utilized in a manner that appropriately protects the confidentiality of the information and the privacy of individuals receiving health care services and items.

“(iii) QUALIFIED IMMUNITY FOR PROVIDING INFORMATION.—The provisions of section 1157(a) (relating to limitation on liability) shall apply to a person providing information to the Secretary or the Attorney General in conjunction with their performance of duties under this section.

“(4) ENSURING ACCESS TO DOCUMENTATION.—The Inspector General of the Department of Health and Human Services is authorized to exercise such authority described in paragraphs (3) through (9) of section 6 of the Inspector General Act of 1978 (5 U.S.C.App.) as necessary with respect to the activities under the fraud and abuse control program established under this subsection.

“(5) AUTHORITY OF INSPECTOR GENERAL.—Nothing in this Act shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978 (5 U.S.C.App.).

“(b) ADDITIONAL USE OF FUNDS BY INSPECTOR GENERAL.—

“(1) REIMBURSEMENTS FOR INVESTIGATIONS.—The Inspector General of the Department of Health and Human Services is authorized to receive and retain for current use reimbursement for the costs of conducting investigations and audits and for monitoring compliance plans when such costs are ordered by a court, voluntarily agreed to by the payor, or otherwise.

“(2) CREDITING.—Funds received by the Inspector General under paragraph (1) as reimbursement for costs of conducting investigations shall be deposited to the credit of the appropriation from which initially paid, or to appropriations for similar purposes currently available at the time of deposit, and shall remain available for obligation for 1 year from the date of the deposit of such funds.

“(c) HEALTH PLAN DEFINED.—For purposes of this section, the term ‘health plan’ means a plan or program that provides health benefits, whether directly, through insurance, or otherwise, and includes—

“(1) a policy of health insurance;

“(2) a contract of a service benefit organization; and

“(3) a membership agreement with a health maintenance organization or other prepaid health plan.”.

<< 42 USCA § 1395i >>

(b) ESTABLISHMENT OF HEALTH CARE FRAUD AND ABUSE CONTROL ACCOUNT IN FEDERAL HOSPITAL INSURANCE TRUST FUND.—Section 1817 (42 U.S.C. 1395i) is amended by adding at the end the following new subsection:

“(k) HEALTH CARE FRAUD AND ABUSE CONTROL ACCOUNT.—

“(1) ESTABLISHMENT.—There is hereby established in the Trust Fund an expenditure account to be known as the ‘Health Care Fraud and Abuse Control Account’ (in this subsection referred to as the ‘Account’).

“(2) APPROPRIATED AMOUNTS TO TRUST FUND.—

“(A) IN GENERAL.—There are hereby appropriated to the Trust Fund—

“(i) such gifts and bequests as may be made as provided in subparagraph (B);

“(ii) such amounts as may be deposited in the Trust Fund as provided in sections 242(b) and 249(c) of the Health Insurance Portability and Accountability Act of 1996, and title XI; and

“(iii) such amounts as are transferred to the Trust Fund under subparagraph (C).

“(B) AUTHORIZATION TO ACCEPT GIFTS.—The Trust Fund is authorized to accept on behalf of the United States money gifts and bequests made unconditionally to the Trust Fund, for the benefit of the Account or any activity financed through the Account.

“(C) TRANSFER OF AMOUNTS.—The Managing Trustee shall transfer to the Trust Fund, under rules similar to the rules in section 9601 of the Internal Revenue Code of 1986, an amount equal to the sum of the following:

“(i) Criminal fines recovered in cases involving a Federal health care offense (as defined in section 982(a)(6)(B) of title 18, United States Code).

“(ii) Civil monetary penalties and assessments imposed in health care cases, including amounts recovered under titles XI, XVIII, and XIX, and chapter 38 of title 31, United States Code (except as otherwise provided by law).

“(iii) Amounts resulting from the forfeiture of property by reason of a Federal health care offense.

“(iv) Penalties and damages obtained and otherwise creditable to miscellaneous receipts of the general fund of the Treasury obtained under sections 3729 through 3733 of title 31, United States Code (known as the False Claims Act), in cases involving claims related to the provision of health care items and services (other than funds awarded to a relator, for restitution or otherwise authorized by law).

“(D) APPLICATION.—Nothing in subparagraph (C)(iii) shall be construed to limit the availability of recoveries and forfeitures obtained under title I of the Employee Retirement Income Security Act of 1974 for the purpose of providing equitable or remedial relief for employee welfare benefit plans, and for participants and beneficiaries under such plans, as authorized under such title.

“(3) APPROPRIATED AMOUNTS TO ACCOUNT FOR FRAUD AND ABUSE CONTROL PROGRAM, ETC.—

“(A) DEPARTMENTS OF HEALTH AND HUMAN SERVICES AND JUSTICE.—

“(i) IN GENERAL.—There are hereby appropriated to the Account from the Trust Fund such sums as the Secretary and the Attorney General certify are necessary to carry out the purposes described in subparagraph (C), to be available without further appropriation, in an amount not to exceed—

“(I) for fiscal year 1997, \$104,000,000,

“(II) for each of the fiscal years 1998 through 2003, the limit for the preceding fiscal year, increased by 15 percent; and

“(III) for each fiscal year after fiscal year 2003, the limit for fiscal year 2003.

“(ii) MEDICARE AND MEDICAID ACTIVITIES.—For each fiscal year, of the amount appropriated in clause (i), the following amounts shall be available only for the purposes of the activities of the Office of the Inspector General of the Department of Health and Human Services with respect to the Medicare and medicaid programs—

“(I) for fiscal year 1997, not less than \$60,000,000 and not more than \$70,000,000;

“(II) for fiscal year 1998, not less than \$80,000,000 and not more than \$90,000,000;

“(III) for fiscal year 1999, not less than \$90,000,000 and not more than \$100,000,000;

“(IV) for fiscal year 2000, not less than \$110,000,000 and not more than \$120,000,000;

“(V) for fiscal year 2001, not less than \$120,000,000 and not more than \$130,000,000;

“(VI) for fiscal year 2002, not less than \$140,000,000 and not more than \$150,000,000; and

“(VII) for each fiscal year after fiscal year 2002, not less than \$150,000,000 and not more than \$160,000,000.

“(B) FEDERAL BUREAU OF INVESTIGATION.—There are hereby appropriated from the general fund of the United States Treasury and hereby appropriated to the Account for transfer to the Federal Bureau of Investigation to carry out the purposes described in subparagraph (C), to be available without further appropriation—

“(i) for fiscal year 1997, \$47,000,000;

“(ii) for fiscal year 1998, \$56,000,000;

“(iii) for fiscal year 1999, \$66,000,000;

“(iv) for fiscal year 2000, \$76,000,000;

“(v) for fiscal year 2001, \$88,000,000;

“(vi) for fiscal year 2002, \$101,000,000; and

“(vii) for each fiscal year after fiscal year 2002, \$114,000,000.

“(C) USE OF FUNDS.—The purposes described in this subparagraph are to cover the costs (including equipment, salaries and benefits, and travel and training) of the administration and operation of the health care fraud and abuse control program established under section 1128C(a), including the costs of—

“(i) prosecuting health care matters (through criminal, civil, and administrative proceedings);

“(ii) investigations;

“(iii) financial and performance audits of health care programs and operations;

“(iv) inspections and other evaluations; and

“(v) provider and consumer education regarding compliance with the provisions of title XI.

“(4) APPROPRIATED AMOUNTS TO ACCOUNT FOR MEDICARE INTEGRITY PROGRAM.—

“(A) IN GENERAL.—There are hereby appropriated to the Account from the Trust Fund for each fiscal year such amounts as are necessary to carry out the Medicare Integrity Program under section 1893, subject to subparagraph (B) and to be available without further appropriation.

“(B) AMOUNTS SPECIFIED.—The amount appropriated under subparagraph (A) for a fiscal year is as follows:

“(i) For fiscal year 1997, such amount shall be not less than \$430,000,000 and not more than \$440,000,000.

“(ii) For fiscal year 1998, such amount shall be not less than \$490,000,000 and not more than \$500,000,000.

“(iii) For fiscal year 1999, such amount shall be not less than \$550,000,000 and not more than \$560,000,000.

“(iv) For fiscal year 2000, such amount shall be not less than \$620,000,000 and not more than \$630,000,000.

“(v) For fiscal year 2001, such amount shall be not less than \$670,000,000 and not more than \$680,000,000.

“(vi) For fiscal year 2002, such amount shall be not less than \$690,000,000 and not more than \$700,000,000.

“(vii) For each fiscal year after fiscal year 2002, such amount shall be not less than \$710,000,000 and not more than \$720,000,000.

“(5) ANNUAL REPORT.—Not later than January 1, the Secretary and the Attorney General shall submit jointly a report to Congress which identifies—

“(A) the amounts appropriated to the Trust Fund for the previous fiscal year under paragraph (2)(A) and the source of such amounts; and

“(B) the amounts appropriated from the Trust Fund for such year under paragraph (3) and the justification for the expenditure of such amounts.

“(6) GAO REPORT.—Not later than January 1 of 2000, 2002, and 2004, the Comptroller General of the United States shall submit a report to Congress which—

“(A) identifies—

“(i) the amounts appropriated to the Trust Fund for the previous two fiscal years under paragraph (2)(A) and the source of such amounts; and

“(ii) the amounts appropriated from the Trust Fund for such fiscal years under paragraph (3) and the justification for the expenditure of such amounts;

“(B) identifies any expenditures from the Trust Fund with respect to activities not involving the Medicare program under title XVIII;

“(C) identifies any savings to the Trust Fund, and any other savings, resulting from expenditures from the Trust Fund; and

“(D) analyzes such other aspects of the operation of the Trust Fund as the Comptroller General of the United States considers appropriate.”.

SEC. 202. MEDICARE INTEGRITY PROGRAM.

(a) ESTABLISHMENT OF MEDICARE INTEGRITY PROGRAM.—Title XVIII is amended by adding at the end the following new section:

<< 42 USCA § 1395ddd >>

“MEDICARE INTEGRITY PROGRAM

“SEC. 1893. (a) ESTABLISHMENT OF PROGRAM.—There is hereby established the Medicare Integrity Program (in this section referred to as the ‘Program’) under which the Secretary shall promote the integrity of the Medicare program by entering into contracts in accordance with this section with eligible entities to carry out the activities described in subsection (b).

“(b) ACTIVITIES DESCRIBED.—The activities described in this subsection are as follows:

“(1) Review of activities of providers of services or other individuals and entities furnishing items and services for which payment may be made under this title (including skilled nursing facilities and home health agencies), including medical and utilization review and fraud review (employing similar standards, processes, and technologies used by private health plans, including equipment and software technologies which surpass the capability of the equipment and technologies used in the review of claims under this title as of the date of the enactment of this section).

“(2) Audit of cost reports.

“(3) Determinations as to whether payment should not be, or should not have been, made under this title by reason of section 1862(b), and recovery of payments that should not have been made.

“(4) Education of providers of services, beneficiaries, and other persons with respect to payment integrity and benefit quality assurance issues.

“(5) Developing (and periodically updating) a list of items of durable medical equipment in accordance with section 1834(a) (15) which are subject to prior authorization under such section.

“(c) ELIGIBILITY OF ENTITIES.—An entity is eligible to enter into a contract under the Program to carry out any of the activities described in subsection (b) if—

“(1) the entity has demonstrated capability to carry out such activities;

“(2) in carrying out such activities, the entity agrees to cooperate with the Inspector General of the Department of Health and Human Services, the Attorney General, and other law enforcement agencies, as appropriate, in the investigation and deterrence of fraud and abuse in relation to this title and in other cases arising out of such activities;

“(3) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement; and

“(4) the entity meets such other requirements as the Secretary may impose.

In the case of the activity described in subsection (b)(5), an entity shall be deemed to be eligible to enter into a contract under the Program to carry out the activity if the entity is a carrier with a contract in effect under section 1842.

“(d) PROCESS FOR ENTERING INTO CONTRACTS.—The Secretary shall enter into contracts under the Program in accordance with such procedures as the Secretary shall by regulation establish, except that such procedures shall include the following:

“(1) Procedures for identifying, evaluating, and resolving organizational conflicts of interest that are generally applicable to Federal acquisition and procurement.

“(2) Competitive procedures to be used—

“(A) when entering into new contracts under this section;

“(B) when entering into contracts that may result in the elimination of responsibilities of an individual fiscal intermediary or carrier under section 202(b) of the Health Insurance Portability and Accountability Act of 1996; and

“(C) at any other time considered appropriate by the Secretary,

except that the Secretary may continue to contract with entities that are carrying out the activities described in this section pursuant to agreements under section 1816 or contracts under section 1842 in effect on the date of the enactment of this section.

“(3) Procedures under which a contract under this section may be renewed without regard to any provision of law requiring competition if the contractor has met or exceeded the performance requirements established in the current contract.

The Secretary may enter into such contracts without regard to final rules having been promulgated.

“(e) LIMITATION ON CONTRACTOR LIABILITY.—The Secretary shall by regulation provide for the limitation of a contractor's liability for actions taken to carry out a contract under the Program, and such regulation shall, to the extent the Secretary finds appropriate, employ the same or comparable standards and other substantive and procedural provisions as are contained in section 1157.”.

(b) ELIMINATION OF FI AND CARRIER RESPONSIBILITY FOR CARRYING OUT ACTIVITIES SUBJECT TO PROGRAM.—

<< 42 USCA § 1395h >>

(1) RESPONSIBILITIES OF FISCAL INTERMEDIARIES UNDER PART A.—Section 1816 (42 U.S.C. 1395h) is amended by adding at the end the following new subsection:

“(l) No agency or organization may carry out (or receive payment for carrying out) any activity pursuant to an agreement under this section to the extent that the activity is carried out pursuant to a contract under the Medicare Integrity Program under section 1893.”.

<< 42 USCA § 1395u >>

(2) RESPONSIBILITIES OF CARRIERS UNDER PART B.—Section 1842(c) (42 U.S.C. 1395u(c)) is amended by adding at the end the following new paragraph:

“(6) No carrier may carry out (or receive payment for carrying out) any activity pursuant to a contract under this subsection to the extent that the activity is carried out pursuant to a contract under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).”.

<< 42 USCA § 1395b–5 >>

SEC. 203. BENEFICIARY INCENTIVE PROGRAMS.

(a) CLARIFICATION OF REQUIREMENT TO PROVIDE EXPLANATION OF MEDICARE BENEFITS.—The Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall provide an explanation of benefits under the Medicare program under title XVIII of the Social Security Act with respect to each item or service for which payment may be

made under the program which is furnished to an individual, without regard to whether or not a deductible or coinsurance may be imposed against the individual with respect to the item or service.

(b) PROGRAM TO COLLECT INFORMATION ON FRAUD AND ABUSE.—

(1) ESTABLISHMENT OF PROGRAM.—Not later than 3 months after the date of the enactment of this Act, the Secretary shall establish a program under which the Secretary shall encourage individuals to report to the Secretary information on individuals and entities who are engaging in or who have engaged in acts or omissions which constitute grounds for the imposition of a sanction under section 1128, 1128A, or 1128B of the Social Security Act, or who have otherwise engaged in fraud and abuse against the Medicare program under title XVIII of such act for which there is a sanction provided under law. The program shall discourage provision of, and not consider, information which is frivolous or otherwise not relevant or material to the imposition of such a sanction.

(2) PAYMENT OF PORTION OF AMOUNTS COLLECTED.—If an individual reports information to the Secretary under the program established under paragraph (1) which serves as the basis for the collection by the Secretary or the Attorney General of any amount of at least \$100 (other than any amount paid as a penalty under section 1128B of the Social Security Act), the Secretary may pay a portion of the amount collected to the individual (under procedures similar to those applicable under section 7623 of the Internal Revenue Code of 1986 to payments to individuals providing information on violations of such Code).

(c) PROGRAM TO COLLECT INFORMATION ON PROGRAM EFFICIENCY.—

(1) ESTABLISHMENT OF PROGRAM.—Not later than 3 months after the date of the enactment of this Act, the Secretary shall establish a program under which the Secretary shall encourage individuals to submit to the Secretary suggestions on methods to improve the efficiency of the Medicare program.

(2) PAYMENT OF PORTION OF PROGRAM SAVINGS.—If an individual submits a suggestion to the Secretary under the program established under paragraph (1) which is adopted by the Secretary and which results in savings to the program, the Secretary may make a payment to the individual of such amount as the Secretary considers appropriate.

SEC. 204. APPLICATION OF CERTAIN HEALTH ANTIFRAUD AND ABUSE SANCTIONS TO FRAUD AND ABUSE AGAINST FEDERAL HEALTH CARE PROGRAMS.

<< 42 USCA § 1320a-7b >>

(a) IN GENERAL.—Section 1128B (42 U.S.C. 1320a-7b) is amended as follows:

(1) In the heading, by striking “MEDICARE OR STATE HEALTH CARE PROGRAMS” and inserting “FEDERAL HEALTH CARE PROGRAMS”.

(2) In subsection (a)(1), by striking “a program under title XVIII or a State health care program (as defined in section 1128(h))” and inserting “a Federal health care program (as defined in subsection (f))”.

(3) In subsection (a)(5), by striking “a program under title XVIII or a State health care program” and inserting “a Federal health care program”.

(4) In the second sentence of subsection (a)—

(A) by striking “a State plan approved under title XIX” and inserting “a Federal health care program”, and

(B) by striking “the State may at its option (notwithstanding any other provision of that title or of such plan)” and inserting “the administrator of such program may at its option (notwithstanding any other provision of such program)”.

(5) In subsection (b), by striking “title XVIII or a State health care program” each place it appears and inserting “a Federal health care program”.

(6) In subsection (c), by inserting “(as defined in section 1128(h))” after “a State health care program”.

(7) By adding at the end the following new subsection:

“(f) For purposes of this section, the term ‘Federal health care program’ means—

“(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5, United States Code); or

“(2) any State health care program, as defined in section 1128(h).”.

<< 42 USCA § 1320a-7b NOTE >>

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 1997.

SEC. 205. GUIDANCE REGARDING APPLICATION OF HEALTH CARE FRAUD AND ABUSE SANCTIONS.

Title XI (42 U.S.C. 1301 et seq.), as amended by section 201, is amended by inserting after section 1128C the following new section:

<< 42 USCA § 1320a-7d >>

“GUIDANCE REGARDING APPLICATION OF HEALTH CARE FRAUD AND ABUSE SANCTIONS

“SEC. 1128d. (a) SOLICITATION AND PUBLICATION OF MODIFICATIONS TO EXISTING SAFE HARBORS AND NEW SAFE HARBORS.—

“(1) IN GENERAL.—

“(A) SOLICITATION OF PROPOSALS FOR SAFE HARBORS.—Not later than January 1, 1997, and not less than annually thereafter, the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60-day period, for—

“(i) modifications to existing safe harbors issued pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 (42 U.S.C. 1320a-7b note);

“(ii) additional safe harbors specifying payment practices that shall not be treated as a criminal offense under section 1128B(b) and shall not serve as the basis for an exclusion under section 1128(b)(7);

“(iii) advisory opinions to be issued pursuant to subsection (b); and

“(iv) special fraud alerts to be issued pursuant to subsection (c).

“(B) PUBLICATION OF PROPOSED MODIFICATIONS AND PROPOSED ADDITIONAL SAFE HARBORS.—After considering the proposals described in clauses (i) and (ii) of subparagraph (A), the Secretary, in consultation with the Attorney General, shall publish in the Federal Register proposed modifications to existing safe harbors and proposed additional safe harbors, if appropriate, with a 60-day comment period. After considering any public comments received during this period, the Secretary shall issue final rules modifying the existing safe harbors and establishing new safe harbors, as appropriate.

“(C) REPORT.—The Inspector General of the Department of Health and Human Services (in this section referred to as the ‘Inspector General’) shall, in an annual report to Congress or as part of the year-end semiannual report required by section 5 of the Inspector General Act of 1978 (5 U.S.C.App.), describe the proposals received under clauses (i) and (ii) of subparagraph (A) and explain which proposals were included in the publication described in subparagraph (B), which proposals were not included in that publication, and the reasons for the rejection of the proposals that were not included.

“(2) CRITERIA FOR MODIFYING AND ESTABLISHING SAFE HARBORS.—In modifying and establishing safe harbors under paragraph (1)(B), the Secretary may consider the extent to which providing a safe harbor for the specified payment practice may result in any of the following:

“(A) An increase or decrease in access to health care services.

“(B) An increase or decrease in the quality of health care services.

“(C) An increase or decrease in patient freedom of choice among health care providers.

“(D) An increase or decrease in competition among health care providers.

“(E) An increase or decrease in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

“(F) An increase or decrease in the cost to Federal health care programs (as defined in section 1128B(f)).

“(G) An increase or decrease in the potential overutilization of health care services.

“(H) The existence or nonexistence of any potential financial benefit to a health care professional or provider which may vary based on their decisions of—

“(i) whether to order a health care item or service; or

“(ii) whether to arrange for a referral of health care items or services to a particular practitioner or provider.

“(I) Any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs (as so defined).

“(b) ADVISORY OPINIONS.—

“(1) ISSUANCE OF ADVISORY OPINIONS.—The Secretary, in consultation with the Attorney General, shall issue written advisory opinions as provided in this subsection.

“(2) MATTERS SUBJECT TO ADVISORY OPINIONS.—The Secretary shall issue advisory opinions as to the following matters:

“(A) What constitutes prohibited remuneration within the meaning of section 1128B(b).

“(B) Whether an arrangement or proposed arrangement satisfies the criteria set forth in section 1128B(b)(3) for activities which do not result in prohibited remuneration.

“(C) Whether an arrangement or proposed arrangement satisfies the criteria which the Secretary has established, or shall establish by regulation for activities which do not result in prohibited remuneration.

“(D) What constitutes an inducement to reduce or limit services to individuals entitled to benefits under title XVIII or title XIX within the meaning of section 1128B(b).

“(E) Whether any activity or proposed activity constitutes grounds for the imposition of a sanction under section 1128, 1128A, or 1128B.

“(3) MATTERS NOT SUBJECT TO ADVISORY OPINIONS.—Such advisory opinions shall not address the following matters:

“(A) Whether the fair market value shall be, or was paid or received for any goods, services or property.

“(B) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

“(4) EFFECT OF ADVISORY OPINIONS.—

“(A) BINDING AS TO SECRETARY AND PARTIES INVOLVED.—Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion.

“(B) FAILURE TO SEEK OPINION.—The failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A, or 1128B.

“(5) REGULATIONS.—

“(A) IN GENERAL.—Not later than 180 days after the date of the enactment of this section, the Secretary shall issue regulations to carry out this section. Such regulations shall provide for—

“(i) the procedure to be followed by a party applying for an advisory opinion;

“(ii) the procedure to be followed by the Secretary in responding to a request for an advisory opinion;

“(iii) the interval in which the Secretary shall respond;

“(iv) the reasonable fee to be charged to the party requesting an advisory opinion; and

“(v) the manner in which advisory opinions will be made available to the public.

“(B) SPECIFIC CONTENTS.—Under the regulations promulgated pursuant to subparagraph (A)—

“(i) the Secretary shall be required to issue to a party requesting an advisory opinion by not later than 60 days after the request is received; and

“(ii) the fee charged to the party requesting an advisory opinion shall be equal to the costs incurred by the Secretary in responding to the request.

“(6) APPLICATION OF SUBSECTION.—This subsection shall apply to requests for advisory opinions made on or after the date which is 6 months after the date of enactment of this section and before the date which is 4 years after such date of enactment.

“(c) SPECIAL FRAUD ALERTS.—

“(1) IN GENERAL.—

“(A) REQUEST FOR SPECIAL FRAUD ALERTS.—Any person may present, at any time, a request to the Inspector General for a notice which informs the public of practices which the Inspector General considers to be suspect or of particular concern under the Medicare program under title XVIII or a State health care program, as defined in section 1128(h) (in this subsection referred to as a ‘special fraud alert’).

“(B) ISSUANCE AND PUBLICATION OF SPECIAL FRAUD ALERTS.—Upon receipt of a request described in subparagraph (A), the Inspector General shall investigate the subject matter of the request to determine whether a special fraud alert should be issued. If appropriate, the Inspector General shall issue a special fraud alert in response to the request. All special fraud alerts issued pursuant to this subparagraph shall be published in the Federal Register.

“(2) CRITERIA FOR SPECIAL FRAUD ALERTS.—In determining whether to issue a special fraud alert upon a request described in paragraph (1), the Inspector General may consider—

“(A) whether and to what extent the practices that would be identified in the special fraud alert may result in any of the consequences described in subsection (a)(2); and

“(B) the volume and frequency of the conduct that would be identified in the special fraud alert.”.

Subtitle B—Revisions to Current Sanctions for Fraud and Abuse

<< 42 USCA § 1320a-7 >>

SEC. 211. MANDATORY EXCLUSION FROM PARTICIPATION IN MEDICARE AND STATE HEALTH CARE PROGRAMS.

(a) INDIVIDUAL CONVICTED OF FELONY RELATING TO HEALTH CARE FRAUD.—

(1) IN GENERAL.—Section 1128(a) (42 U.S.C. 1320a-7(a)) is amended by adding at the end the following new paragraph:

“(3) FELONY CONVICTION RELATING TO HEALTH CARE FRAUD.—Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program (other than those specifically described in paragraph (1)) operated by or financed in whole or in part by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.”.

(2) CONFORMING AMENDMENT.—Paragraph (1) of section 1128(b) (42 U.S.C. 1320a-7(b)) is amended to read as follows:

“(1) CONVICTION RELATING TO FRAUD.—Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, under Federal or State law—

“(A) of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

“(i) in connection with the delivery of a health care item or service, or

“(ii) with respect to any act or omission in a health care program (other than those specifically described in subsection (a) (1)) operated by or financed in whole or in part by any Federal, State, or local government agency; or

“(B) of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program (other than a health care program) operated by or financed in whole or in part by any Federal, State, or local government agency.”.

(b) INDIVIDUAL CONVICTED OF FELONY RELATING TO CONTROLLED SUBSTANCE.—

(1) IN GENERAL.—Section 1128(a) (42 U.S.C. 1320a-7(a)), as amended by subsection (a), is amended by adding at the end the following new paragraph:

“(4) FELONY CONVICTION RELATING TO CONTROLLED SUBSTANCE.—Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, under Federal or State law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.”.

(2) CONFORMING AMENDMENT.—Section 1128(b)(3) (42 U.S.C. 1320a-7(b)(3)) is amended—

(A) in the heading, by striking “CONVICTION” and inserting “MISDEMEANOR CONVICTION”; and

(B) by striking “criminal offense” and inserting “criminal offense consisting of a misdemeanor”.

<< 42 USCA § 1320a-7 >>

SEC. 212. ESTABLISHMENT OF MINIMUM PERIOD OF EXCLUSION FOR CERTAIN INDIVIDUALS AND ENTITIES SUBJECT TO PERMISSIVE EXCLUSION FROM MEDICARE AND STATE HEALTH CARE PROGRAMS.

Section 1128(c)(3) (42 U.S.C. 1320a-7(c)(3)) is amended by adding at the end the following new subparagraphs:

“(D) In the case of an exclusion of an individual or entity under paragraph (1), (2), or (3) of subsection (b), the period of the exclusion shall be 3 years, unless the Secretary determines in accordance with published regulations that a shorter period is appropriate because of mitigating circumstances or that a longer period is appropriate because of aggravating circumstances.

“(E) In the case of an exclusion of an individual or entity under subsection (b)(4) or (b)(5), the period of the exclusion shall not be less than the period during which the individual's or entity's license to provide health care is revoked, suspended, or surrendered, or the individual or the entity is excluded or suspended from a Federal or State health care program.

“(F) In the case of an exclusion of an individual or entity under subsection (b)(6)(B), the period of the exclusion shall be not less than 1 year.”.

<< 42 USCA § 1320a-7 >>

SEC. 213. PERMISSIVE EXCLUSION OF INDIVIDUALS WITH OWNERSHIP OR CONTROL INTEREST IN SANCTIONED ENTITIES.

Section 1128(b) (42 U.S.C. 1320a-7(b)) is amended by adding at the end the following new paragraph:

“(15) INDIVIDUALS CONTROLLING A SANCTIONED ENTITY.—

(A) Any individual—

“(i) who has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know (as defined in section 1128A(i)(6)) of the action constituting the basis for the conviction or exclusion described in subparagraph (B); or

“(ii) who is an officer or managing employee (as defined in section 1126(b)) of such an entity.

“(B) For purposes of subparagraph (A), the term ‘sanctioned entity’ means an entity—

“(i) that has been convicted of any offense described in subsection (a) or in paragraph (1), (2), or (3) of this subsection; or

“(ii) that has been excluded from participation under a program under title XVIII or under a State health care program.”.

<< 42 USCA § 1320c-5 >>

SEC. 214. SANCTIONS AGAINST PRACTITIONERS AND PERSONS FOR FAILURE TO COMPLY WITH STATUTORY OBLIGATIONS.

(a) MINIMUM PERIOD OF EXCLUSION FOR PRACTITIONERS AND PERSONS FAILING TO MEET STATUTORY OBLIGATIONS.—

(1) IN GENERAL.—The second sentence of section 1156(b)(1) (42 U.S.C. 1320c-5(b)(1)) is amended by striking “may prescribe)” and inserting “may prescribe, except that such period may not be less than 1 year)”.

(2) CONFORMING AMENDMENT.—Section 1156(b)(2) (42 U.S.C. 1320c-5(b)(2)) is amended by striking “shall remain” and inserting “shall (subject to the minimum period specified in the second sentence of paragraph (1)) remain”.

(b) REPEAL OF “UNWILLING OR UNABLE” CONDITION FOR IMPOSITION OF SANCTION.—Section 1156(b)(1) (42 U.S.C. 1320c-5(b)(1)) is amended—

(1) in the second sentence, by striking “and determines” and all that follows through “such obligations,”; and

(2) by striking the third sentence.

SEC. 215. INTERMEDIATE SANCTIONS FOR MEDICARE HEALTH MAINTENANCE ORGANIZATIONS.

<< 42 USCA § 1395mm >>

(a) APPLICATION OF INTERMEDIATE SANCTIONS FOR ANY PROGRAM VIOLATIONS.—

(1) IN GENERAL.—Section 1876(i)(1) (42 U.S.C. 1395mm(i)(1)) is amended by striking “the Secretary may terminate” and all that follows and inserting “in accordance with procedures established under paragraph (9), the Secretary may at any time

terminate any such contract or may impose the intermediate sanctions described in paragraph (6)(B) or (6)(C) (whichever is applicable) on the eligible organization if the Secretary determines that the organization—

“(A) has failed substantially to carry out the contract;

“(B) is carrying out the contract in a manner substantially inconsistent with the efficient and effective administration of this section; or

“(C) no longer substantially meets the applicable conditions of subsections (b), (c), (e), and (f).”.

(2) OTHER INTERMEDIATE SANCTIONS FOR MISCELLANEOUS PROGRAM VIOLATIONS.—Section 1876(i)(6) (42 U.S.C. 1395mm(i)(6)) is amended by adding at the end the following new subparagraph:

“(C) In the case of an eligible organization for which the Secretary makes a determination under paragraph (1), the basis of which is not described in subparagraph (A), the Secretary may apply the following intermediate sanctions:

“(i) Civil money penalties of not more than \$25,000 for each determination under paragraph (1) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

“(ii) Civil money penalties of not more than \$10,000 for each week beginning after the initiation of procedures by the Secretary under paragraph (9) during which the deficiency that is the basis of a determination under paragraph (1) exists.

“(iii) Suspension of enrollment of individuals under this section after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.”.

(3) PROCEDURES FOR IMPOSING SANCTIONS.—Section 1876(i) (42 U.S.C. 1395mm(i)) is amended by adding at the end the following new paragraph:

“(9) The Secretary may terminate a contract with an eligible organization under this section or may impose the intermediate sanctions described in paragraph (6) on the organization in accordance with formal investigation and compliance procedures established by the Secretary under which—

“(A) the Secretary first provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under paragraph (1) and the organization fails to develop or implement such a plan;

“(B) in deciding whether to impose sanctions, the Secretary considers aggravating factors such as whether an organization has a history of deficiencies or has not taken action to correct deficiencies the Secretary has brought to the organization's attention;

“(C) there are no unreasonable or unnecessary delays between the finding of a deficiency and the imposition of sanctions; and

“(D) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before imposing any sanction or terminating the contract.”.

(4) CONFORMING AMENDMENTS.—Section 1876(i)(6)(B) (42 U.S.C. 1395mm(i)(6)(B)) is amended by striking the second sentence.

(b) AGREEMENTS WITH PEER REVIEW ORGANIZATIONS.—Section 1876(i)(7)(A) (42 U.S.C. 1395mm(i)(7)(A)) is amended by striking “an agreement” and inserting “a written agreement”.

<< 42 USCA § 1395mm NOTE >>

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to contract years beginning on or after January 1, 1997.

SEC. 216. ADDITIONAL EXCEPTION TO ANTI-KICKBACK PENALTIES FOR RISK-SHARING ARRANGEMENTS.

<< 42 USCA § 1320a-7b >>

(a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C. 1320a-7b(b)(3)) is amended—

(1) by striking “and” at the end of subparagraph (D);

(2) by striking the period at the end of subparagraph (E) and inserting “; and”; and

(3) by adding at the end the following new subparagraph:

“(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible

organization under section 1876 or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide.”.

<< 42 USCA § 1320a-7b NOTE >>

(b) NEGOTIATED RULEMAKING FOR RISK-SHARING EXCEPTION.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the “Secretary”) shall establish, on an expedited basis and using a negotiated rulemaking process under subchapter 3 of chapter 5 of title 5, United States Code, standards relating to the exception for risk-sharing arrangements to the antikickback penalties described in section 1128B(b)(3)(F) of the Social Security Act, as added by subsection (a).

(B) FACTORS TO CONSIDER.—In establishing standards relating to the exception for risk-sharing arrangements to the anti-kickback penalties under subparagraph (A), the Secretary—

(i) shall consult with the Attorney General and representatives of the hospital, physician, other health practitioner, and health plan communities, and other interested parties; and

(ii) shall take into account—

(I) the level of risk appropriate to the size and type of arrangement;

(II) the frequency of assessment and distribution of incentives;

(III) the level of capital contribution; and

(IV) the extent to which the risk-sharing arrangement provides incentives to control the cost and quality of health care services.

(2) PUBLICATION OF NOTICE.—In carrying out the rule-making process under this subsection, the Secretary shall publish the notice provided for under section 564(a) of title 5, United States Code, by not later than 45 days after the date of the enactment of this Act.

(3) TARGET DATE FOR PUBLICATION OF RULE.—As part of the notice under paragraph (2), and for purposes of this subsection, the “target date for publication” (referred to in section 564(a)(5) of such title) shall be January 1, 1997.

(4) ABBREVIATED PERIOD FOR SUBMISSION OF COMMENTS.—In applying section 564(c) of such title under this subsection, “15 days” shall be substituted for “30 days”.

(5) APPOINTMENT OF NEGOTIATED RULEMAKING COMMITTEE AND FACILITATOR.—The Secretary shall provide for—

(A) the appointment of a negotiated rulemaking committee under section 565(a) of such title by not later than 30 days after the end of the comment period provided for under section 564(c) of such title (as shortened under paragraph (4)), and

(B) the nomination of a facilitator under section 566(c) of such title by not later than 10 days after the date of appointment of the committee.

(6) PRELIMINARY COMMITTEE REPORT.—The negotiated rule-making committee appointed under paragraph (5) shall report to the Secretary, by not later than October 1, 1996, regarding the committee's progress on achieving a consensus with regard to the rulemaking proceeding and whether such consensus is likely to occur before one month before the target date for publication of the rule. If the committee reports that the committee has failed to make significant progress toward such consensus or is unlikely to reach such consensus by the target date, the Secretary may terminate such process and provide for the publication of a rule under this subsection through such other methods as the Secretary may provide.

(7) FINAL COMMITTEE REPORT.—If the committee is not terminated under paragraph (6), the rulemaking committee shall submit a report containing a proposed rule by not later than one month before the target publication date.

(8) INTERIM, FINAL EFFECT.—The Secretary shall publish a rule under this subsection in the Federal Register by not later than the target publication date. Such rule shall be effective and final immediately on an interim basis, but is subject to change and revision after public notice and opportunity for a period (of not less than 60 days) for public comment. In connection with such rule, the Secretary shall specify the process for the timely review and approval of applications of entities to be certified as provider-sponsored organizations pursuant to such rules and consistent with this subsection.

(9) PUBLICATION OF RULE AFTER PUBLIC COMMENT.—The Secretary shall provide for consideration of such comments and republication of such rule by not later than 1 year after the target publication date.

<< 42 USCA § 1320a-7b NOTE >>

(c) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to written agreements entered into on or after January 1, 1997, without regard to whether regulations have been issued to implement such amendments.

<< 42 USCA § 1320a-7b >>

SEC. 217. CRIMINAL PENALTY FOR FRAUDULENT DISPOSITION OF ASSETS IN ORDER TO OBTAIN MEDICAID BENEFITS.

Section 1128B(a) (42 U.S.C. 1320a-7b(a)) is amended—

- (1) by striking “or” at the end of paragraph (4);
- (2) by adding “or” at the end of paragraph (5); and
- (3) by inserting after paragraph (5) the following new paragraph:

“(6) knowingly and willfully disposes of assets (including by any transfer in trust) in order for an individual to become eligible for medical assistance under a State plan under title XIX, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1917(c).”.

<< 42 USCA §§ 1320a-7 NOTE, 1320a-7b nt, 1320c-5 nt, 1395mm nt >>

SEC. 218. EFFECTIVE DATE.

Except as otherwise provided, the amendments made by this subtitle shall take effect January 1, 1997.

Subtitle C—Data Collection

SEC. 221. ESTABLISHMENT OF THE HEALTH CARE FRAUD AND ABUSE DATA COLLECTION PROGRAM.

(a) IN GENERAL.—Title XI (42 U.S.C. 1301 et seq.), as amended by sections 201 and 205, is amended by inserting after section 1128D the following new section:

<< 42 USCA § 1320a-7e >>

“HEALTH CARE FRAUD AND ABUSE DATA COLLECTION PROGRAM

“SEC. 1128E. (a) GENERAL PURPOSE.—Not later than January 1, 1997, the Secretary shall establish a national health care fraud and abuse data collection program for the reporting of final adverse actions (not including settlements in which no findings of liability have been made) against health care providers, suppliers, or practitioners as required by subsection (b), with access as set forth in subsection (c), and shall maintain a database of the information collected under this section.

“(b) REPORTING OF INFORMATION.—

“(1) IN GENERAL.—Each Government agency and health plan shall report any final adverse action (not including settlements in which no findings of liability have been made) taken against a health care provider, supplier, or practitioner.

“(2) INFORMATION TO BE REPORTED.—The information to be reported under paragraph (1) includes:

“(A) The name and TIN (as defined in section 7701(a)(41) of the Internal Revenue Code of 1986) of any health care provider, supplier, or practitioner who is the subject of a final adverse action.

“(B) The name (if known) of any health care entity with which a health care provider, supplier, or practitioner, who is the subject of a final adverse action, is affiliated or associated.

“(C) The nature of the final adverse action and whether such action is on appeal.

“(D) A description of the acts or omissions and injuries upon which the final adverse action was based, and such other information as the Secretary determines by regulation is required for appropriate interpretation of information reported under this section.

“(3) CONFIDENTIALITY.—In determining what information is required, the Secretary shall include procedures to assure that the privacy of individuals receiving health care services is appropriately protected.

“(4) TIMING AND FORM OF REPORTING.—The information required to be reported under this subsection shall be reported regularly (but not less often than monthly) and in such form and manner as the Secretary prescribes. Such information shall first be required to be reported on a date specified by the Secretary.

“(5) TO WHOM REPORTED.—The information required to be reported under this subsection shall be reported to the Secretary.

“(c) DISCLOSURE AND CORRECTION OF INFORMATION.—

“(1) DISCLOSURE.—With respect to the information about final adverse actions (not including settlements in which no findings of liability have been made) reported to the Secretary under this section with respect to a health care provider, supplier, or practitioner, the Secretary shall, by regulation, provide for—

“(A) disclosure of the information, upon request, to the health care provider, supplier, or licensed practitioner, and

“(B) procedures in the case of disputed accuracy of the information.

“(2) CORRECTIONS.—Each Government agency and health plan shall report corrections of information already reported about any final adverse action taken against a health care provider, supplier, or practitioner, in such form and manner that the Secretary prescribes by regulation.

“(d) ACCESS TO REPORTED INFORMATION.—

“(1) AVAILABILITY.—The information in the database maintained under this section shall be available to Federal and State government agencies and health plans pursuant to procedures that the Secretary shall provide by regulation.

“(2) FEES FOR DISCLOSURE.—The Secretary may establish or approve reasonable fees for the disclosure of information in such database (other than with respect to requests by Federal agencies). The amount of such a fee shall be sufficient to recover the full costs of operating the database. Such fees shall be available to the Secretary or, in the Secretary's discretion to the agency designated under this section to cover such costs.

“(e) PROTECTION FROM LIABILITY FOR REPORTING.—No person or entity, including the agency designated by the Secretary in subsection (b)(5) shall be held liable in any civil action with respect to any report made as required by this section, without knowledge of the falsity of the information contained in the report.

“(f) COORDINATION WITH NATIONAL PRACTITIONER DATA BANK.—The Secretary shall implement this section in such a manner as to avoid duplication with the reporting requirements established for the National Practitioner Data Bank under the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 et seq.).

“(g) DEFINITIONS AND SPECIAL RULES.—For purposes of this section:

“(1) FINAL ADVERSE ACTION.—

“(A) IN GENERAL.—The term ‘final adverse action’ includes:

“(i) Civil judgments against a health care provider, supplier, or practitioner in Federal or State court related to the delivery of a health care item or service.

“(ii) Federal or State criminal convictions related to the delivery of a health care item or service.

“(iii) Actions by Federal or State agencies responsible for the licensing and certification of health care providers, suppliers, and licensed health care practitioners, including—

“(I) formal or official actions, such as revocation or suspension of a license (and the length of any such suspension), reprimand, censure or probation,

“(II) any other loss of license or the right to apply for, or renew, a license of the provider, supplier, or practitioner, whether by operation of law, voluntary surrender, non-renewability, or otherwise, or

“(III) any other negative action or finding by such Federal or State agency that is publicly available information.

“(iv) Exclusion from participation in Federal or State health care programs (as defined in sections 1128B(f) and 1128(h), respectively).

“(v) Any other adjudicated actions or decisions that the Secretary shall establish by regulation.

“(B) EXCEPTION.—The term does not include any action with respect to a malpractice claim.

“(2) PRACTITIONER.—The terms ‘licensed health care practitioner’, ‘licensed practitioner’, and ‘practitioner’ mean, with respect to a State, an individual who is licensed or otherwise authorized by the State to provide health care services (or any individual who, without authority holds himself or herself out to be so licensed or authorized).

“(3) GOVERNMENT AGENCY.—The term ‘Government agency’ shall include:

“(A) The Department of Justice.

“(B) The Department of Health and Human Services.

“(C) Any other Federal agency that either administers or provides payment for the delivery of health care services, including, but not limited to the Department of Defense and the Veterans' Administration.

“(D) State law enforcement agencies.

“(E) State medicaid fraud control units.

“(F) Federal or State agencies responsible for the licensing and certification of health care providers and licensed health care practitioners.

“(4) HEALTH PLAN.—The term ‘health plan’ has the meaning given such term by section 1128C(c).

“(5) DETERMINATION OF CONVICTION.—For purposes of paragraph (1), the existence of a conviction shall be determined under paragraph (4) of section 1128(i).”.

<< 42 USCA § 1395u >>

(b) IMPROVED PREVENTION IN ISSUANCE OF MEDICARE PROVIDER NUMBERS.—Section 1842(r) (42 U.S.C. 1395u(r)) is amended by adding at the end the following new sentence: “Under such system, the Secretary may impose appropriate fees on such physicians to cover the costs of investigation and recertification activities with respect to the issuance of the identifiers.”.

Subtitle D—Civil Monetary Penalties

SEC. 231. SOCIAL SECURITY ACT CIVIL MONETARY PENALTIES.

<< 42 USCA § 1320a-7a >>

(a) GENERAL CIVIL MONETARY PENALTIES.—Section 1128A (42 U.S.C. 1320a-7a) is amended as follows:

(1) In the third sentence of subsection (a), by striking “programs under title XVIII” and inserting “Federal health care programs (as defined in section 1128B(f)(1))”.

(2) In subsection (f)—

(A) by redesignating paragraph (3) as paragraph (4); and

(B) by inserting after paragraph (2) the following new paragraph:

“(3) With respect to amounts recovered arising out of a claim under a Federal health care program (as defined in section 1128B(f)), the portion of such amounts as is determined to have been paid by the program shall be repaid to the program, and the portion of such amounts attributable to the amounts recovered under this section by reason of the amendments made by the Health Insurance Portability and Accountability Act of 1996 (as estimated by the Secretary) shall be deposited into the Federal Hospital Insurance Trust Fund pursuant to section 1817(k)(2)(C).”.

(3) In subsection (i)—

(A) in paragraph (2), by striking “title V, XVIII, XIX, or XX of this Act” and inserting “a Federal health care program (as defined in section 1128B(f))”,

(B) in paragraph (4), by striking “a health insurance or medical services program under title XVIII or XIX of this Act” and inserting “a Federal health care program (as so defined)”, and

(C) in paragraph (5), by striking “title V, XVIII, XIX, or XX” and inserting “a Federal health care program (as so defined)”.

(4) By adding at the end the following new subsection:

“(m)(1) For purposes of this section, with respect to a Federal health care program not contained in this Act, references to the Secretary in this section shall be deemed to be references to the Secretary or Administrator of the department or agency with jurisdiction over such program and references to the Inspector General of the Department of Health and Human Services in this section shall be deemed to be references to the Inspector General of the applicable department or agency.

“(2)(A) The Secretary and Administrator of the departments and agencies referred to in paragraph (1) may include in any action pursuant to this section, claims within the jurisdiction of other Federal departments or agencies as long as the following conditions are satisfied:

“(i) The case involves primarily claims submitted to the Federal health care programs of the department or agency initiating the action.

“(ii) The Secretary or Administrator of the department or agency initiating the action gives notice and an opportunity to participate in the investigation to the Inspector General of the department or agency with primary jurisdiction over the Federal health care programs to which the claims were submitted.

“(B) If the conditions specified in subparagraph (A) are fulfilled, the Inspector General of the department or agency initiating the action is authorized to exercise all powers granted under the Inspector General Act of 1978 (5 U.S.C.App.) with respect to the claims submitted to the other departments or agencies to the same manner and extent as provided in that Act with respect to claims submitted to such departments or agencies.”.

(b) EXCLUDED INDIVIDUAL RETAINING OWNERSHIP OR CONTROL INTEREST IN PARTICIPATING ENTITY.—Section 1128A(a) (42 U.S.C. 1320a–7a(a)) is amended—

- (1) by striking “or” at the end of paragraph (1)(D);
- (2) by striking “, or” at the end of paragraph (2) and inserting a semicolon;
- (3) by striking the semicolon at the end of paragraph (3) and inserting “; or”; and
- (4) by inserting after paragraph (3) the following new paragraph:

“(4) in the case of a person who is not an organization, agency, or other entity, is excluded from participating in a program under title XVIII or a State health care program in accordance with this subsection or under section 1128 and who, at the time of a violation of this subsection—

“(A) retains a direct or indirect ownership or control interest in an entity that is participating in a program under title XVIII or a State health care program, and who knows or should know of the action constituting the basis for the exclusion; or

“(B) is an officer or managing employee (as defined in section 1126(b)) of such an entity;”.

(c) MODIFICATIONS OF AMOUNTS OF PENALTIES AND ASSESSMENTS.—Section 1128A(a) (42 U.S.C. 1320a–7a(a)), as amended by subsection (b), is amended in the matter following paragraph (4)—

- (1) by striking “\$2,000” and inserting “\$10,000”;
- (2) by inserting “; in cases under paragraph (4), \$10,000 for each day the prohibited relationship occurs” after “false or misleading information was given”; and
- (3) by striking “twice the amount” and inserting “3 times the amount”.

(d) CLARIFICATION OF LEVEL OF KNOWLEDGE REQUIRED FOR IMPOSITION OF CIVIL MONETARY PENALTIES.—

(1) IN GENERAL.—Section 1128A(a) (42 U.S.C. 1320a–7a(a)) is amended—

- (A) in paragraphs (1) and (2), by inserting “knowingly” before “presents” each place it appears; and
- (B) in paragraph (3), by striking “gives” and inserting “knowingly gives or causes to be given”.

(2) DEFINITION OF STANDARD.—Section 1128A(i) (42 U.S.C. 1320a–7a(i)), as amended by subsection (h)(2), is amended by adding at the end the following new paragraph:

“(7) The term ‘should know’ means that a person, with respect to information—

- “(A) acts in deliberate ignorance of the truth or falsity of the information; or
- “(B) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.”.

(e) CLAIM FOR ITEM OR SERVICE BASED ON INCORRECT CODING OR MEDICALLY UNNECESSARY SERVICES.—Section 1128A(a)(1) (42 U.S.C. 1320a–7a(a)(1)), as amended by subsection (b), is amended—

(1) in subparagraph (A) by striking “claimed,” and inserting “claimed, including any person who engages in a pattern or practice of presenting or causing to be presented a claim for an item or service that is based on a code that the person knows or should know will result in a greater payment to the person than the code the person knows or should know is applicable to the item or service actually provided,”;

- (2) in subparagraph (C), by striking “or” at the end;
- (3) in subparagraph (D), by striking the semicolon and inserting “, or”; and
- (4) by inserting after subparagraph (D) the following new subparagraph:

“(E) is for a pattern of medical or other items or services that a person knows or should know are not medically necessary;”.

<< 42 USCA § 1320c–5 >>

(f) SANCTIONS AGAINST PRACTITIONERS AND PERSONS FOR FAILURE TO COMPLY WITH STATUTORY OBLIGATIONS.—Section 1156(b)(3) (42 U.S.C. 1320c–5(b)(3)) is amended by striking “the actual or estimated cost” and inserting “up to \$10,000 for each instance”.

<< 42 USCA § 1395mm >>

(g) PROCEDURAL PROVISIONS.—Section 1876(i)(6) (42 U.S.C. 1395mm(i)(6)), as amended by section 215(a)(2), is amended by adding at the end the following new subparagraph:

“(D) The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under subparagraph (B)(i) or (C)(i) in the same manner as such provisions apply to a civil money penalty or proceeding under section 1128A(a).”.

<< 42 USCA § 1320a–7a >>

(h) PROHIBITION AGAINST OFFERING INDUCEMENTS TO INDIVIDUALS ENROLLED UNDER PROGRAMS OR PLANS.—

(1) OFFER OF REMUNERATION.—Section 1128A(a) (42 U.S.C. 1320a–7a(a)), as amended by subsection (b), is amended

—
(A) by striking “or” at the end of paragraph (3);

(B) by striking the semicolon at the end of paragraph (4) and inserting “; or”; and

(C) by inserting after paragraph (4) the following new paragraph:

“(5) offers to or transfers remuneration to any individual eligible for benefits under title XVIII of this Act, or under a State health care program (as defined in section 1128(h)) that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under title XVIII, or a State health care program (as so defined);”.

(2) REMUNERATION DEFINED.—Section 1128A(i) (42 U.S.C. 1320a–7a(i)) is amended by adding at the end the following new paragraph:

“(6) The term ‘remuneration’ includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term ‘remuneration’ does not include—

“(A) the waiver of coinsurance and deductible amounts by a person, if—

“(i) the waiver is not offered as part of any advertisement or solicitation;

“(ii) the person does not routinely waive coinsurance or deductible amounts; and

“(iii) the person—

“(I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need;

“(II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts; or

“(III) provides for any permissible waiver as specified in section 1128B(b)(3) or in regulations issued by the Secretary;

“(B) differentials in coinsurance and deductible amounts as part of a benefit plan design as long as the differentials have been disclosed in writing to all beneficiaries, third party payers, and providers, to whom claims are presented and as long as the differentials meet the standards as defined in regulations promulgated by the Secretary not later than 180 days after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996; or

“(C) incentives given to individuals to promote the delivery of preventive care as determined by the Secretary in regulations so promulgated.”.

<< 42 USCA §§ 1320a–7a NOTE, 1320c–5 nt, 1395mm nt >>

(i) EFFECTIVE DATE.—The amendments made by this section shall apply to acts or omissions occurring on or after January 1, 1997.

SEC. 232. PENALTY FOR FALSE CERTIFICATION FOR HOME HEALTH SERVICES.

<< 42 USCA § 1320a–7a >>

(a) IN GENERAL.—Section 1128A(b) (42 U.S.C. 1320a–7a(b)) is amended by adding at the end the following new paragraph:

“(3)(A) Any physician who executes a document described in subparagraph (B) with respect to an individual knowing that all of the requirements referred to in such subparagraph are not met with respect to the individual shall be subject to a civil monetary penalty of not more than the greater of—

“(i) \$5,000, or

“(ii) three times the amount of the payments under title XVIII for home health services which are made pursuant to such certification.

“(B) A document described in this subparagraph is any document that certifies, for purposes of title XVIII, that an individual meets the requirements of section 1814(a)(2)(C) or 1835(a)(2)(A) in the case of home health services furnished to the individual.”.

<< 42 USCA § 1320a–7a NOTE >>

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to certifications made on or after the date of the enactment of this Act.

Subtitle E—Revisions to Criminal Law

SEC. 241. DEFINITIONS RELATING TO FEDERAL HEALTH CARE OFFENSE.

<< 18 USCA § 24 >>

(a) IN GENERAL.—Chapter 1 of title 18, United States Code, is amended by adding at the end the following:

“§ 24. Definitions relating to Federal health care offense

“(a) As used in this title, the term ‘Federal health care offense’ means a violation of, or a criminal conspiracy to violate—

“(1) section 669, 1035, 1347, or 1518 of this title;

“(2) section 287, 371, 664, 666, 1001, 1027, 1341, 1343, or 1954 of this title, if the violation or conspiracy relates to a health care benefit program.

“(b) As used in this title, the term ‘health care benefit program’ means any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.”.

<< 18 USCA Ch. 1 >>

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 2 of title 18, United States Code, is amended by inserting after the item relating to section 23 the following new item:

“24. Definitions relating to Federal health care offense.”.

SEC. 242. HEALTH CARE FRAUD.

(a) OFFENSE.—

(1) IN GENERAL.—Chapter 63 of title 18, United States Code, is amended by adding at the end the following:

<< 18 USCA § 1347 >>

“§ 1347. Health care fraud

“Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice—

“(1) to defraud any health care benefit program; or

“(2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program,

in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 10 years, or both. If the violation results in serious bodily injury (as defined in section 1365 of this title), such person shall be fined under this title or imprisoned not more than 20 years, or both; and if the violation results in death, such person shall be fined under this title, or imprisoned for any term of years or for life, or both.”.

(2) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 63 of title 18, United States Code, is amended by adding at the end the following:

<< 18 USCA Ch. 63 >>

“1347. Health care fraud.”.

<< 42 USCA § 1395i NOTE >>

(b) CRIMINAL FINES DEPOSITED IN FEDERAL HOSPITAL INSURANCE TRUST FUND.—The Secretary of the Treasury shall deposit into the Federal Hospital Insurance Trust Fund pursuant to section 1817(k)(2)(C) of the Social Security Act (42 U.S.C. 1395i) an amount equal to the criminal fines imposed under section 1347 of title 18, United States Code (relating to health care fraud).

SEC. 243. THEFT OR EMBEZZLEMENT.

<< 18 USCA § 669 >>

(a) IN GENERAL.—Chapter 31 of title 18, United States Code, is amended by adding at the end the following:

“§ 669. Theft or embezzlement in connection with health care

“(a) Whoever knowingly and willfully embezzles, steals, or otherwise without authority converts to the use of any person other than the rightful owner, or intentionally misapplies any of the moneys, funds, securities, premiums, credits, property, or other assets of a health care benefit program, shall be fined under this title or imprisoned not more than 10 years, or both; but if the value of such property does not exceed the sum of \$100 the defendant shall be fined under this title or imprisoned not more than one year, or both.

“(b) As used in this section, the term ‘health care benefit program’ has the meaning given such term in section 24(b) of this title.”.

<< 18 USCA Ch. 31 >>

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 31 of title 18, United States Code, is amended by adding at the end the following:

“669. Theft or embezzlement in connection with health care.”.

SEC. 244. FALSE STATEMENTS.

<< 18 USCA § 1035 >>

(a) IN GENERAL.—Chapter 47 of title 18, United States Code, is amended by adding at the end the following:

“§ 1035. False statements relating to health care matters

“(a) Whoever, in any matter involving a health care benefit program, knowingly and willfully—

“(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or

“(2) makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry,

in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 5 years, or both.

“(b) As used in this section, the term ‘health care benefit program’ has the meaning given such term in section 24(b) of this title.”.

<< 18 USCA Ch. 47 >>

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 47 of title 18, United States Code, is amended by adding at the end the following new item:

“1035. False statements relating to health care matters.”.

SEC. 245. OBSTRUCTION OF CRIMINAL INVESTIGATIONS OF HEALTH CARE OFFENSES.

<< 18 USCA § 1518 >>

(a) IN GENERAL.—Chapter 73 of title 18, United States Code, is amended by adding at the end the following:

“§ 1518. Obstruction of criminal investigations of health care offenses

“(a) Whoever willfully prevents, obstructs, misleads, delays or attempts to prevent, obstruct, mislead, or delay the communication of information or records relating to a violation of a Federal health care offense to a criminal investigator shall be fined under this title or imprisoned not more than 5 years, or both.

“(b) As used in this section the term ‘criminal investigator’ means any individual duly authorized by a department, agency, or armed force of the United States to conduct or engage in investigations for prosecutions for violations of health care offenses.”.

<< 18 USCA Ch. 73 >>

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 73 of title 18, United States Code, is amended by adding at the end the following new item:

“1518. Obstruction of criminal investigations of health care offenses.”.

<< 18 USCA § 1956 >>

SEC. 246. LAUNDERING OF MONETARY INSTRUMENTS.

Section 1956(c)(7) of title 18, United States Code, is amended by adding at the end the following:

“(F) Any act or activity constituting an offense involving a Federal health care offense.”.

<< 18 USCA § 1345 >>

SEC. 247. INJUNCTIVE RELIEF RELATING TO HEALTH CARE OFFENSES.

(a) IN GENERAL.—Section 1345(a)(1) of title 18, United States Code, is amended—

(1) by striking “or” at the end of subparagraph (A);

(2) by inserting “or” at the end of subparagraph (B); and

(3) by adding at the end the following:

“(C) committing or about to commit a Federal health care offense.”.

(b) FREEZING OF ASSETS.—Section 1345(a)(2) of title 18, United States Code, is amended by inserting “or a Federal health care offense” after “title”).

SEC. 248. AUTHORIZED INVESTIGATIVE DEMAND PROCEDURES.

<< 18 USCA § 3486 >>

(a) IN GENERAL.—Chapter 223 of title 18, United States Code, is amended by adding after section 3485 the following:

“§ 3486. Authorized investigative demand procedures

“(a) AUTHORIZATION.—(1) In any investigation relating to any act or activity involving a Federal health care offense, the Attorney General or the Attorney General's designee may issue in writing and cause to be served a subpoena—

“(A) requiring the production of any records (including any books, papers, documents, electronic media, or other objects or tangible things), which may be relevant to an authorized law enforcement inquiry, that a person or legal entity may possess or have care, custody, or control; or

“(B) requiring a custodian of records to give testimony concerning the production and authentication of such records.

“(2) A subpoena under this subsection shall describe the objects required to be produced and prescribe a return date within a reasonable period of time within which the objects can be assembled and made available.

“(3) The production of records shall not be required under this section at any place more than 500 miles distant from the place where the subpoena for the production of such records is served.

“(4) Witnesses summoned under this section shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

“(b) SERVICE.—A subpoena issued under this section may be served by any person who is at least 18 years of age and is designated in the subpoena to serve it. Service upon a natural person may be made by personal delivery of the subpoena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpoena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpoena entered on a true copy thereof by the person serving it shall be proof of service.

“(c) ENFORCEMENT.—In the case of contumacy by or refusal to obey a subpoena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpoenaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subpoena. The court may issue an order requiring the subpoenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony concerning the production and authentication of such records. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

“(d) IMMUNITY FROM CIVIL LIABILITY.—Notwithstanding any Federal, State, or local law, any person, including officers, agents, and employees, receiving a summons under this section, who complies in good faith with the summons and thus produces the materials sought, shall not be liable in any court of any State or the United States to any customer or other person for such production or for nondisclosure of that production to the customer.

“(e) LIMITATION ON USE.—(1) Health information about an individual that is disclosed under this section may not be used in, or disclosed to any person for use in, any administrative, civil, or criminal action or investigation directed against the individual who is the subject of the information unless the action or investigation arises out of and is directly related to receipt of health care or payment for health care or action involving a fraudulent claim related to health; or if authorized by an appropriate order of a court of competent jurisdiction, granted after application showing good cause therefor.

“(2) In assessing good cause, the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services.

“(3) Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.”.

<< 18 USCA Ch. 223 >>

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 223 of title 18, United States Code, is amended by inserting after the item relating to section 3485 the following new item:

“3486. Authorized investigative demand procedures.”.

<< 18 USCA § 1510 >>

(c) CONFORMING AMENDMENT.—Section 1510(b)(3)(B) of title 18, United States Code, is amended by inserting “or a Department of Justice subpoena (issued under section 3486 of title 18),” after “subpoena”.

SEC. 249. FORFEITURES FOR FEDERAL HEALTH CARE OFFENSES.

<< 18 USCA § 982 >>

(a) IN GENERAL.—Section 982(a) of title 18, United States Code, is amended by adding after paragraph (5) the following new paragraph:

“(6) The court, in imposing sentence on a person convicted of a Federal health care offense, shall order the person to forfeit property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.”.

(b) CONFORMING AMENDMENT.—Section 982(b)(1)(A) of title 18, United States Code, is amended by inserting “or (a)(6)” after “(a)(1)”.

<< 42 USCA § 1395i NOTE >>

(c) PROPERTY FORFEITED DEPOSITED IN FEDERAL HOSPITAL INSURANCE TRUST FUND.—

(1) IN GENERAL.—After the payment of the costs of asset forfeiture has been made and after all restoration payments (if any) have been made, and notwithstanding any other provision of law, the Secretary of the Treasury shall deposit into the Federal Hospital Insurance Trust Fund pursuant to section 1817(k)(2)(C) of the Social Security Act, as added by section 301(b), an amount equal to the net amount realized from the forfeiture of property by reason of a Federal health care offense pursuant to section 982(a)(6) of title 18, United States Code.

(2) COSTS OF ASSET FORFEITURE.—For purposes of paragraph (1), the term “payment of the costs of asset forfeiture” means—

(A) the payment, at the discretion of the Attorney General, of any expenses necessary to seize, detain, inventory, safeguard, maintain, advertise, sell, or dispose of property under seizure, detention, or forfeited, or of any other necessary expenses incident to the seizure, detention, forfeiture, or disposal of such property, including payment for—

(i) contract services;

(ii) the employment of outside contractors to operate and manage properties or provide other specialized services necessary to dispose of such properties in an effort to maximize the return from such properties; and

(iii) reimbursement of any Federal, State, or local agency for any expenditures made to perform the functions described in this subparagraph;

(B) at the discretion of the Attorney General, the payment of awards for information or assistance leading to a civil or criminal forfeiture involving any Federal agency participating in the Health Care Fraud and Abuse Control Account;

(C) the compromise and payment of valid liens and mortgages against property that has been forfeited, subject to the discretion of the Attorney General to determine the validity of any such lien or mortgage and the amount of payment to be made, and the employment of attorneys and other personnel skilled in State real estate law as necessary;

(D) payment authorized in connection with remission or mitigation procedures relating to property forfeited; and

(E) the payment of State and local property taxes on forfeited real property that accrued between the date of the violation giving rise to the forfeiture and the date of the forfeiture order.

(3) RESTORATION PAYMENT.—Notwithstanding any other provision of law, if the Federal health care offense referred to in paragraph (1) resulted in a loss to an employee welfare benefit plan within the meaning of section 3(1) of the Employee Retirement Income Security Act of 1974, the Secretary of the Treasury shall transfer to such employee welfare benefit plan,

from the amount realized from the forfeiture of property referred to in paragraph (1), an amount equal to such loss. For purposes of paragraph (1), the term “restoration payment” means the amount transferred to an employee welfare benefit plan pursuant to this paragraph.

<< 29 USCA § 1136 NOTE >>

SEC. 250. RELATION TO ERISA AUTHORITY.

Nothing in this subtitle shall be construed as affecting the authority of the Secretary of Labor under section 506(b) of the Employee Retirement Income Security Act of 1974, including the Secretary's authority with respect to violations of title 18, United States Code (as amended by this subtitle).

Subtitle F—Administrative Simplification

<< 42 USCA § 1320d NOTE >>

SEC. 261. PURPOSE.

It is the purpose of this subtitle to improve the Medicare program under title XVIII of the Social Security Act, the medicaid program under title XIX of such Act, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information.

SEC. 262. ADMINISTRATIVE SIMPLIFICATION.

(a) IN GENERAL.—Title XI (42 U.S.C. 1301 et seq.) is amended by adding at the end the following:

<< 42 USCA Ch. 7 >>

“PART C—ADMINISTRATIVE SIMPLIFICATION

<< 42 USCA § 1320d >>

“DEFINITIONS

“SEC. 1171. For purposes of this part:

“(1) CODE SET.—The term ‘code set’ means any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes.

“(2) HEALTH CARE CLEARINGHOUSE.—The term ‘health care clearinghouse’ means a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements.

“(3) HEALTH CARE PROVIDER.—The term ‘health care provider’ includes a provider of services (as defined in section 1861(u)), a provider of medical or other health services (as defined in section 1861(s)), and any other person furnishing health care services or supplies.

“(4) HEALTH INFORMATION.—The term ‘health information’ means any information, whether oral or recorded in any form or medium, that—

“(A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

“(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

“(5) HEALTH PLAN.—The term ‘health plan’ means an individual or group plan that provides, or pays the cost of, medical care (as such term is defined in section 2791 of the Public Health Service Act). Such term includes the following, and any combination thereof:

“(A) A group health plan (as defined in section 2791(a) of the Public Health Service Act), but only if the plan—

“(i) has 50 or more participants (as defined in section 3(7) of the Employee Retirement Income Security Act of 1974); or

“(ii) is administered by an entity other than the employer who established and maintains the plan.

“(B) A health insurance issuer (as defined in section 2791(b) of the Public Health Service Act).

“(C) A health maintenance organization (as defined in section 2791(b) of the Public Health Service Act).

“(D) Part A or part B of the Medicare program under title XVIII.

“(E) The medicaid program under title XIX.

“(F) A Medicare supplemental policy (as defined in section 1882(g)(1)).

“(G) A long-term care policy, including a nursing home fixed indemnity policy (unless the Secretary determines that such a policy does not provide sufficiently comprehensive coverage of a benefit so that the policy should be treated as a health plan).

“(H) An employee welfare benefit plan or any other arrangement which is established or maintained for the purpose of offering or providing health benefits to the employees of 2 or more employers.

“(I) The health care program for active military personnel under title 10, United States Code.

“(J) The veterans health care program under chapter 17 of title 38, United States Code.

“(K) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in section 1072(4) of title 10, United States Code.

“(L) The Indian health service program under the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

“(M) The Federal Employees Health Benefit Plan under chapter 89 of title 5, United States Code.

“(6) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.—The term ‘individually identifiable health information’ means any information, including demographic information collected from an individual, that—

“(A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

“(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and—

“(i) identifies the individual; or

“(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

“(7) STANDARD.—The term ‘standard’, when used with reference to a data element of health information or a transaction referred to in section 1173(a)(1), means any such data element or transaction that meets each of the standards and implementation specifications adopted or established by the Secretary with respect to the data element or transaction under sections 1172 through 1174.

“(8) STANDARD SETTING ORGANIZATION.—The term ‘standard setting organization’ means a standard setting organization accredited by the American National Standards Institute, including the National Council for Prescription Drug Programs, that develops standards for information transactions, data elements, or any other standard that is necessary to, or will facilitate, the implementation of this part.

<< 42 USCA § 1320d-1 >>

“GENERAL REQUIREMENTS FOR ADOPTION OF STANDARDS

“SEC. 1172. (a) APPLICABILITY.—Any standard adopted under this part shall apply, in whole or in part, to the following persons:

“(1) A health plan.

“(2) A health care clearinghouse.

“(3) A health care provider who transmits any health information in electronic form in connection with a transaction referred to in section 1173(a)(1).

“(b) REDUCTION OF COSTS.—Any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.

“(c) ROLE OF STANDARD SETTING ORGANIZATIONS.—

“(1) IN GENERAL.—Except as provided in paragraph (2), any standard adopted under this part shall be a standard that has been developed, adopted, or modified by a standard setting organization.

“(2) SPECIAL RULES.—

“(A) DIFFERENT STANDARDS.—The Secretary may adopt a standard that is different from any standard developed, adopted, or modified by a standard setting organization, if—

“(i) the different standard will substantially reduce administrative costs to health care providers and health plans compared to the alternatives; and

“(ii) the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5, United States Code.

“(B) NO STANDARD BY STANDARD SETTING ORGANIZATION.—If no standard setting organization has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under this part—

“(i) paragraph (1) shall not apply; and

“(ii) subsection (f) shall apply.

“(3) CONSULTATION REQUIREMENT.—

“(A) IN GENERAL.—A standard may not be adopted under this part unless—

“(i) in the case of a standard that has been developed, adopted, or modified by a standard setting organization, the organization consulted with each of the organizations described in subparagraph (B) in the course of such development, adoption, or modification; and

“(ii) in the case of any other standard, the Secretary, in complying with the requirements of subsection (f), consulted with each of the organizations described in subparagraph (B) before adopting the standard.

“(B) ORGANIZATIONS DESCRIBED.—The organizations referred to in subparagraph (A) are the following:

“(i) The National Uniform Billing Committee.

“(ii) The National Uniform Claim Committee.

“(iii) The Workgroup for Electronic Data Interchange.

“(iv) The American Dental Association.

“(d) IMPLEMENTATION SPECIFICATIONS.—The Secretary shall establish specifications for implementing each of the standards adopted under this part.

“(e) PROTECTION OF TRADE SECRETS.—Except as otherwise required by law, a standard adopted under this part shall not require disclosure of trade secrets or confidential commercial information by a person required to comply with this part.

“(f) ASSISTANCE TO THE SECRETARY.—In complying with the requirements of this part, the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)), and shall consult with appropriate Federal and State agencies and private organizations. The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a standard under this part.

“(g) APPLICATION TO MODIFICATIONS OF STANDARDS.—This section shall apply to a modification to a standard (including an addition to a standard) adopted under section 1174(b) in the same manner as it applies to an initial standard adopted under section 1174(a).

<< 42 USCA § 1320d-2 >>

“STANDARDS FOR INFORMATION TRANSACTIONS AND DATA ELEMENTS

“SEC. 1173. (a) STANDARDS TO ENABLE ELECTRONIC EXCHANGE.—

“(1) IN GENERAL.—The Secretary shall adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for—

“(A) the financial and administrative transactions described in paragraph (2); and

“(B) other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs.

“(2) TRANSACTIONS.—The transactions referred to in paragraph (1)(A) are transactions with respect to the following:

“(A) Health claims or equivalent encounter information.

“(B) Health claims attachments.

“(C) Enrollment and disenrollment in a health plan.

“(D) Eligibility for a health plan.

“(E) Health care payment and remittance advice.

“(F) Health plan premium payments.

“(G) First report of injury.

“(H) Health claim status.

“(I) Referral certification and authorization.

“(3) ACCOMMODATION OF SPECIFIC PROVIDERS.—The standards adopted by the Secretary under paragraph (1) shall accommodate the needs of different types of health care providers.

“(b) UNIQUE HEALTH IDENTIFIERS.—

“(1) IN GENERAL.—The Secretary shall adopt standards providing for a standard unique health identifier for each individual, employer, health plan, and health care provider for use in the health care system. In carrying out the preceding sentence for each health plan and health care provider, the Secretary shall take into account multiple uses for identifiers and multiple locations and specialty classifications for health care providers.

“(2) USE OF IDENTIFIERS.—The standards adopted under paragraph (1) shall specify the purposes for which a unique health identifier may be used.

“(c) CODE SETS.—

“(1) IN GENERAL.—The Secretary shall adopt standards that—

“(A) select code sets for appropriate data elements for the transactions referred to in subsection (a)(1) from among the code sets that have been developed by private and public entities; or

“(B) establish code sets for such data elements if no code sets for the data elements have been developed.

“(2) DISTRIBUTION.—The Secretary shall establish efficient and low-cost procedures for distribution (including electronic distribution) of code sets and modifications made to such code sets under section 1174(b).

“(d) SECURITY STANDARDS FOR HEALTH INFORMATION.—

“(1) SECURITY STANDARDS.—The Secretary shall adopt security standards that—

“(A) take into account—

“(i) the technical capabilities of record systems used to maintain health information;

“(ii) the costs of security measures;

“(iii) the need for training persons who have access to health information;

“(iv) the value of audit trails in computerized record systems; and

“(v) the needs and capabilities of small health care providers and rural health care providers (as such providers are defined by the Secretary); and

“(B) ensure that a health care clearinghouse, if it is part of a larger organization, has policies and security procedures which isolate the activities of the health care clearinghouse with respect to processing information in a manner that prevents unauthorized access to such information by such larger organization.

“(2) SAFEGUARDS.—Each person described in section 1172(a) who maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards—

“(A) to ensure the integrity and confidentiality of the information;

“(B) to protect against any reasonably anticipated—

“(i) threats or hazards to the security or integrity of the information; and

“(ii) unauthorized uses or disclosures of the information; and

“(C) otherwise to ensure compliance with this part by the officers and employees of such person.

“(e) ELECTRONIC SIGNATURE.—

“(1) STANDARDS.—The Secretary, in coordination with the Secretary of Commerce, shall adopt standards specifying procedures for the electronic transmission and authentication of signatures with respect to the transactions referred to in subsection (a)(1).

“(2) EFFECT OF COMPLIANCE.—Compliance with the standards adopted under paragraph (1) shall be deemed to satisfy Federal and State statutory requirements for written signatures with respect to the transactions referred to in subsection (a)(1).

“(f) TRANSFER OF INFORMATION AMONG HEALTH PLANS.—The Secretary shall adopt standards for transferring among health plans appropriate standard data elements needed for the coordination of benefits, the sequential processing of claims, and other data elements for individuals who have more than one health plan.

<< 42 USCA § 1320d-3 >>

“TIMETABLES FOR ADOPTION OF STANDARDS

“SEC. 1174. (a) INITIAL STANDARDS.—The Secretary shall carry out section 1173 not later than 18 months after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, except that standards relating to claims attachments shall be adopted not later than 30 months after such date.

“(b) ADDITIONS AND MODIFICATIONS TO STANDARDS.—

“(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall review the standards adopted under section 1173, and shall adopt modifications to the standards (including additions to the standards), as determined appropriate, but not more frequently than once every 12 months. Any addition or modification to a standard shall be completed in a manner which minimizes the disruption and cost of compliance.

“(2) SPECIAL RULES.—

“(A) FIRST 12-MONTH PERIOD.—Except with respect to additions and modifications to code sets under subparagraph (B), the Secretary may not adopt any modification to a standard adopted under this part during the 12-month period beginning on the date the standard is initially adopted, unless the Secretary determines that the modification is necessary in order to permit compliance with the standard.

“(B) ADDITIONS AND MODIFICATIONS TO CODE SETS.—

“(i) IN GENERAL.—The Secretary shall ensure that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets.

“(ii) ADDITIONAL RULES.—If a code set is modified under this subsection, the modified code set shall include instructions on how data elements of health information that were encoded prior to the modification may be converted or translated so as to preserve the informational value of the data elements that existed before the modification. Any modification to a code set under this subsection shall be implemented in a manner that minimizes the disruption and cost of complying with such modification.

<< 42 USCA § 1320d-4 >>

“REQUIREMENTS

“SEC. 1175. (a) CONDUCT OF TRANSACTIONS BY PLANS.—

“(1) IN GENERAL.—If a person desires to conduct a transaction referred to in section 1173(a)(1) with a health plan as a standard transaction—

“(A) the health plan may not refuse to conduct such transaction as a standard transaction;

“(B) the insurance plan may not delay such transaction, or otherwise adversely affect, or attempt to adversely affect, the person or the transaction on the ground that the transaction is a standard transaction; and

“(C) the information transmitted and received in connection with the transaction shall be in the form of standard data elements of health information.

“(2) SATISFACTION OF REQUIREMENTS.—A health plan may satisfy the requirements under paragraph (1) by—

“(A) directly transmitting and receiving standard data elements of health information; or

“(B) submitting nonstandard data elements to a health care clearinghouse for processing into standard data elements and transmission by the health care clearinghouse, and receiving standard data elements through the health care clearinghouse.

“(3) TIMETABLE FOR COMPLIANCE.—Paragraph (1) shall not be construed to require a health plan to comply with any standard, implementation specification, or modification to a standard or specification adopted or established by the Secretary under sections 1172 through 1174 at any time prior to the date on which the plan is required to comply with the standard or specification under subsection (b).

“(b) COMPLIANCE WITH STANDARDS.—

“(1) INITIAL COMPLIANCE.—

“(A) IN GENERAL.—Not later than 24 months after the date on which an initial standard or implementation specification is adopted or established under sections 1172 and 1173, each person to whom the standard or implementation specification applies shall comply with the standard or specification.

“(B) SPECIAL RULE FOR SMALL HEALTH PLANS.—In the case of a small health plan, paragraph (1) shall be applied by substituting ‘36 months’ for ‘24 months’. For purposes of this subsection, the Secretary shall determine the plans that qualify as small health plans.

“(2) COMPLIANCE WITH MODIFIED STANDARDS.—If the Secretary adopts a modification to a standard or implementation specification under this part, each person to whom the standard or implementation specification applies shall comply with the modified standard or implementation specification at such time as the Secretary determines appropriate, taking into account the time needed to comply due to the nature and extent of the modification. The time determined appropriate under the preceding sentence may not be earlier than the last day of the 180-day period beginning on the date such modification is adopted. The Secretary may extend the time for compliance for small health plans, if the Secretary determines that such extension is appropriate.

“(3) CONSTRUCTION.—Nothing in this subsection shall be construed to prohibit any person from complying with a standard or specification by—

“(A) submitting nonstandard data elements to a health care clearinghouse for processing into standard data elements and transmission by the health care clearinghouse; or

“(B) receiving standard data elements through a health care clearinghouse.

<< 42 USCA § 1320d-5 >>

“GENERAL PENALTY FOR FAILURE TO COMPLY WITH REQUIREMENTS AND STANDARDS

“SEC. 1176. (a) GENERAL PENALTY.—

“(1) IN GENERAL.—Except as provided in subsection (b), the Secretary shall impose on any person who violates a provision of this part a penalty of not more than \$100 for each such violation, except that the total amount imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000.

“(2) PROCEDURES.—The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such section 1128A.

“(b) LIMITATIONS.—

“(1) OFFENSES OTHERWISE PUNISHABLE.—A penalty may not be imposed under subsection (a) with respect to an act if the act constitutes an offense punishable under section 1177.

“(2) NONCOMPLIANCE NOT DISCOVERED.—A penalty may not be imposed under subsection (a) with respect to a provision of this part if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision.

“(3) FAILURES DUE TO REASONABLE CAUSE.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), a penalty may not be imposed under subsection (a) if—

“(i) the failure to comply was due to reasonable cause and not to willful neglect; and

“(ii) the failure to comply is corrected during the 30-day period beginning on the first date the person liable for the penalty knew, or by exercising reasonable diligence would have known, that the failure to comply occurred.

“(B) EXTENSION OF PERIOD.—

“(i) NO PENALTY.—The period referred to in subparagraph (A)(ii) may be extended as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

“(ii) ASSISTANCE.—If the Secretary determines that a person failed to comply because the person was unable to comply, the Secretary may provide technical assistance to the person during the period described in subparagraph (A)(ii). Such assistance shall be provided in any manner determined appropriate by the Secretary.

“(4) REDUCTION.—In the case of a failure to comply which is due to reasonable cause and not to willful neglect, any penalty under subsection (a) that is not entirely waived under paragraph (3) may be waived to the extent that the payment of such penalty would be excessive relative to the compliance failure involved.

<< 42 USCA § 1320d-6 >>

“WRONGFUL DISCLOSURE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

“SEC. 1177. (a) OFFENSE.—A person who knowingly and in violation of this part—

“(1) uses or causes to be used a unique health identifier;

“(2) obtains individually identifiable health information relating to an individual; or

“(3) discloses individually identifiable health information to another person,
shall be punished as provided in subsection (b).

“(b) PENALTIES.—A person described in subsection (a) shall—

“(1) be fined not more than \$50,000, imprisoned not more than 1 year, or both;

“(2) if the offense is committed under false pretenses, be fined not more than \$100,000, imprisoned not more than 5 years, or both; and

“(3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than \$250,000, imprisoned not more than 10 years, or both.

<< 42 USCA § 1320d-7 >>

“EFFECT ON STATE LAW

“SEC. 1178. (a) GENERAL EFFECT.—

“(1) GENERAL RULE.—Except as provided in paragraph (2), a provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1172 through 1174, shall supersede any contrary provision of State law, including a provision of State law that requires medical or health plan records (including billing information) to be maintained or transmitted in written rather than electronic form.

“(2) EXCEPTIONS.—A provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1172 through 1174, shall not supersede a contrary provision of State law, if the provision of State law—

“(A) is a provision the Secretary determines—

“(i) is necessary—

“(I) to prevent fraud and abuse;

“(II) to ensure appropriate State regulation of insurance and health plans;

“(III) for State reporting on health care delivery or costs; or

“(IV) for other purposes; or

“(ii) addresses controlled substances; or

“(B) subject to section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996, relates to the privacy of individually identifiable health information.

“(b) PUBLIC HEALTH.—Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

“(c) STATE REGULATORY REPORTING.—Nothing in this part shall limit the ability of a State to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.

<< 42 USCA § 1320d-8 >>

“PROCESSING PAYMENT TRANSACTIONS BY FINANCIAL INSTITUTIONS

“SEC. 1179. To the extent that an entity is engaged in activities of a financial institution (as defined in section 1101 of the Right to Financial Privacy Act of 1978), or is engaged in authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments, for a financial institution, this part, and any standard adopted under this part, shall not apply to the entity with respect to such activities, including the following:

“(1) The use or disclosure of information by the entity for authorizing, processing, clearing, settling, billing, transferring, reconciling or collecting, a payment for, or related to, health plan premiums or health care, where such payment is made by any means, including a credit, debit, or other payment card, an account, check, or electronic funds transfer.

“(2) The request for, or the use or disclosure of, information by the entity with respect to a payment described in paragraph (1)—

“(A) for transferring receivables;

“(B) for auditing;

- “(C) in connection with—
 - “(i) a customer dispute; or
 - “(ii) an inquiry from, or to, a customer;
 - “(D) in a communication to a customer of the entity regarding the customer's transactions, payment card, account, check, or electronic funds transfer;
 - “(E) for reporting to consumer reporting agencies; or
 - “(F) for complying with—
 - “(i) a civil or criminal subpoena; or
 - “(ii) a Federal or State law regulating the entity.”.
- (b) CONFORMING AMENDMENTS.—

<< 42 USCA § 1395cc >>

(1) REQUIREMENT FOR MEDICARE PROVIDERS.—Section 1866(a)(1) (42 U.S.C. 1395cc(a)(1)) is amended—

- (A) by striking “and” at the end of subparagraph (P);
- (B) by striking the period at the end of subparagraph (Q) and inserting “; and”; and
- (C) by inserting immediately after subparagraph (Q) the following new subparagraph:
 - “(R) to contract only with a health care clearinghouse (as defined in section 1171) that meets each standard and implementation specification adopted or established under part C of title XI on or after the date on which the health care clearinghouse is required to comply with the standard or specification.”.

<< 42 USCA Ch. 7 >>

(2) TITLE HEADING.—Title XI (42 U.S.C. 1301 et seq.) is amended by striking the title heading and inserting the following:

“TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION”.

<< 42 USCA § 242k >>

SEC. 263. CHANGES IN MEMBERSHIP AND DUTIES OF NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS.

Section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)) is amended—

- (1) in paragraph (1), by striking “16” and inserting “18”;
- (2) by amending paragraph (2) to read as follows:
 - “(2) The members of the Committee shall be appointed from among persons who have distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Members of the Committee shall be appointed for terms of 4 years.”;
- (3) by redesignating paragraphs (3) through (5) as paragraphs (4) through (6), respectively, and inserting after paragraph (2) the following:
 - “(3) Of the members of the Committee—
 - “(A) 1 shall be appointed, not later than 60 days after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, by the Speaker of the House of Representatives after consultation with the Minority Leader of the House of Representatives;
 - “(B) 1 shall be appointed, not later than 60 days after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, by the President pro tempore of the Senate after consultation with the Minority Leader of the Senate; and
 - “(C) 16 shall be appointed by the Secretary.”;
- (4) by amending paragraph (5) (as so redesignated) to read as follows:

“(5) The Committee—

“(A) shall assist and advise the Secretary—

“(i) to delineate statistical problems bearing on health and health services which are of national or international interest;

“(ii) to stimulate studies of such problems by other organizations and agencies whenever possible or to make investigations of such problems through subcommittees;

“(iii) to determine, approve, and revise the terms, definitions, classifications, and guidelines for assessing health status and health services, their distribution and costs, for use (I) within the Department of Health and Human Services, (II) by all programs administered or funded by the Secretary, including the Federal–State–local cooperative health statistics system referred to in subsection (e), and (III) to the extent possible as determined by the head of the agency involved, by the Department of Veterans Affairs, the Department of Defense, and other Federal agencies concerned with health and health services;

“(iv) with respect to the design of and approval of health statistical and health information systems concerned with the collection, processing, and tabulation of health statistics within the Department of Health and Human Services, with respect to the Cooperative Health Statistics System established under subsection (e), and with respect to the standardized means for the collection of health information and statistics to be established by the Secretary under subsection (j)(1);

“(v) to review and comment on findings and proposals developed by other organizations and agencies and to make recommendations for their adoption or implementation by local, State, national, or international agencies;

“(vi) to cooperate with national committees of other countries and with the World Health Organization and other national agencies in the studies of problems of mutual interest;

“(vii) to issue an annual report on the state of the Nation's health, its health services, their costs and distributions, and to make proposals for improvement of the Nation's health statistics and health information systems; and

“(viii) in complying with the requirements imposed on the Secretary under part C of title XI of the Social Security Act;

“(B) shall study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information;

“(C) shall report to the Secretary not later than 4 years after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996 recommendations and legislative proposals for such standards and electronic exchange; and

“(D) shall be responsible generally for advising the Secretary and the Congress on the status of the implementation of part C of title XI of the Social Security Act.”; and

(5) by adding at the end the following:

“(7) Not later than 1 year after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, and annually thereafter, the Committee shall submit to the Congress, and make public, a report regarding the implementation of part C of title XI of the Social Security Act. Such report shall address the following subjects, to the extent that the Committee determines appropriate:

“(A) The extent to which persons required to comply with part C of title XI of the Social Security Act are cooperating in implementing the standards adopted under such part.

“(B) The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for noncompliance with such standards.

“(C) Whether the Federal and State Governments are receiving information of sufficient quality to meet their responsibilities under such part.

“(D) Any problems that exist with respect to implementation of such part.

“(E) The extent to which timetables under such part are being met.”.

<< 42 USCA § 1320d–2 >>

SEC. 264. RECOMMENDATIONS WITH RESPECT TO PRIVACY OF CERTAIN HEALTH INFORMATION.

(a) IN GENERAL.—Not later than the date that is 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Labor and Human Resources and the Committee on Finance of the Senate and the Committee on Commerce and the Committee on Ways and Means of the House of Representatives detailed recommendations on standards with respect to the privacy of individually identifiable health information.

(b) SUBJECTS FOR RECOMMENDATIONS.—The recommendations under subsection (a) shall address at least the following:

- (1) The rights that an individual who is a subject of individually identifiable health information should have.
- (2) The procedures that should be established for the exercise of such rights.
- (3) The uses and disclosures of such information that should be authorized or required.

(c) REGULATIONS.—

(1) IN GENERAL.—If legislation governing standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act (as added by section 262) is not enacted by the date that is 36 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate final regulations containing such standards not later than the date that is 42 months after the date of the enactment of this Act. Such regulations shall address at least the subjects described in subsection (b).

(2) PREEMPTION.—A regulation promulgated under paragraph (1) shall not supercede a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation.

(d) CONSULTATION.—In carrying out this section, the Secretary of Health and Human Services shall consult with—

- (1) the National Committee on Vital and Health Statistics established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)); and
- (2) the Attorney General.

Subtitle G—Duplication and Coordination of Medicare–Related Plans

SEC. 271. DUPLICATION AND COORDINATION OF MEDICARE–RELATED PLANS.

<< 42 USCA § 1395ss >>

(a) TREATMENT OF CERTAIN HEALTH INSURANCE POLICIES AS NONDUPLICATIVE.—Section 1882(d)(3)(A) (42 U.S.C. 1395ss(d)(3)(A)) is amended—

- (1) in clause (iii), by striking “clause (i)” and inserting “clause (i)(II)”; and
- (2) by adding at the end the following:

“(iv) For purposes of this subparagraph, a health insurance policy (other than a Medicare supplemental policy) providing for benefits which are payable to or on behalf of an individual without regard to other health benefit coverage of such individual is not considered to ‘duplicate’ any health benefits under this title, under title XIX, or under a health insurance policy, and subclauses (I) and (III) of clause (i) do not apply to such a policy.

“(v) For purposes of this subparagraph, a health insurance policy (or a rider to an insurance contract which is not a health insurance policy) is not considered to ‘duplicate’ health benefits under this title or under another health insurance policy if it—

“(I) provides health care benefits only for long-term care, nursing home care, home health care, or community-based care, or any combination thereof,

“(II) coordinates against or excludes items and services available or paid for under this title or under another health insurance policy, and

“(III) for policies sold or issued on or after the end of the 90–day period beginning on the date of enactment of the Health Insurance Portability and Accountability Act of 1996 discloses such coordination or exclusion in the policy's outline of coverage.

For purposes of this clause, the terms ‘coordinates’ and ‘coordination’ mean, with respect to a policy in relation to health benefits under this title or under another health insurance policy, that the policy under its terms is secondary to, or excludes from payment, items and services to the extent available or paid for under this title or under another health insurance policy.

“(vi)(I) An individual entitled to benefits under part A or enrolled under part B of this title who is applying for a health insurance policy (other than a policy described in subclause (III)) shall be furnished a disclosure statement described in clause (vii) for the type of policy being applied for. Such statement shall be furnished as a part of (or together with) the application for such policy.

“(II) Whoever issues or sells a health insurance policy (other than a policy described in subclause (III)) to an individual described in subclause (I) and fails to furnish the appropriate disclosure statement as required under such subclause shall be

fined under title 18, United States Code, or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject to a civil money penalty of not to exceed \$25,000 (or \$15,000 in the case of a person other than the issuer of the policy) for each such violation.

“(III) A policy described in this subclause (to which subclauses (I) and (II) do not apply) is a Medicare supplemental policy or a health insurance policy identified under 60 Federal Register 30880 (June 12, 1995) as a policy not required to have a disclosure statement.

“(IV) Any reference in this section to the revised NAIC model regulation (referred to in subsection (m)(1)(A)) is deemed a reference to such regulation as revised by section 171(m)(2) of the Social Security Act Amendments of 1994 (Public Law 103–432) and as modified by substituting, for the disclosure required under section 16D(2), disclosure under subclause (I) of an appropriate disclosure statement under clause (vii).

“(vii) The disclosure statement described in this clause for a type of policy is the statement specified under subparagraph (D) of this paragraph (as in effect before the date of the enactment of the Health Insurance Portability and Accountability Act of 1996) for that type of policy, as revised as follows:

“(I) In each statement, amend the second line to read as follows:

‘THIS IS NOT MEDICARE SUPPLEMENT INSURANCE’.

“(II) In each statement, strike the third line and insert the following: ‘Some health care services paid for by Medicare may also trigger the payment of benefits under this policy.’.

“(III) In each statement not described in subclause (V), strike the boldface matter that begins ‘This insurance’ and all that follows up to the next paragraph that begins ‘Medicare’.

“(IV) In each statement not described in subclause (V), insert before the boxed matter (that states ‘Before You Buy This Insurance’) the following: ‘This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.’.

“(V) In a statement relating to policies providing both nursing home and non-institutional coverage, to policies providing nursing home benefits only, or policies providing home care benefits only, amend the sentence that begins ‘Federal law’ to read as follows: ‘Federal law requires us to inform you that in certain situations this insurance may pay for some care also covered by Medicare.’.

“(viii)(I) Subject to subclause (II), nothing in this subparagraph shall restrict or preclude a State's ability to regulate health insurance policies, including any health insurance policy that is described in clause (iv), (v), or (vi)(III).

“(II) A State may not declare or specify, in statute, regulation, or otherwise, that a health insurance policy (other than a Medicare supplemental policy) or rider to an insurance contract which is not a health insurance policy, that is described in clause (iv), (v), or (vi)(III) and that is sold, issued, or renewed to an individual entitled to benefits under part A or enrolled under part B ‘duplicates’ health benefits under this title or under a Medicare supplemental policy.”.

(b) CONFORMING AMENDMENTS.—Section 1882(d)(3) (42 U.S.C. 1395ss(d)(3)) is amended—

(1) in subparagraph (C)—

(A) by striking “with respect to (i)” and inserting “with respect to”, and

(B) by striking “, (ii) the sale” and all that follows up to the period at the end; and

(2) by striking subparagraph (D).

<< 42 USCA § 1395ss NOTE >>

(c) TRANSITIONAL PROVISION.—

(1) NO PENALTIES.—Subject to paragraph (3), no criminal or civil money penalty may be imposed under section 1882(d)(3) (A) of the Social Security Act for any act or omission that occurred during the transition period (as defined in paragraph (4)) and that relates to any health insurance policy that is described in clause (iv) or (v) of such section (as amended by subsection (a)).

(2) LIMITATION ON LEGAL ACTION.—Subject to paragraph (3), no legal action shall be brought or continued in any Federal or State court insofar as such action—

(A) includes a cause of action which arose, or which is based on or evidenced by any act or omission which occurred, during the transition period; and

(B) relates to the application of section 1882(d)(3)(A) of the Social Security Act to any act or omission with respect to the sale, issuance, or renewal of any health insurance policy that is described in clause (iv) or (v) of such section (as amended by subsection (a)).

(3) DISCLOSURE CONDITION.—In the case of a policy described in clause (iv) of section 1882(d)(3)(A) of the Social Security Act that is sold or issued on or after the effective date of statements under section 171(d)(3)(C) of the Social Security Act Amendments of 1994 and before the end of the 30-day period beginning on the date of the enactment of this Act, paragraphs (1) and (2) shall only apply if disclosure was made in accordance with section 1882(d)(3)(C)(ii) of the Social Security Act (as in effect before the date of the enactment of this Act).

(4) TRANSITION PERIOD.—In this subsection, the term “transition period” means the period beginning on November 5, 1991, and ending on the date of the enactment of this Act.

<< 42 USCA § 1395ss NOTE >>

(d) EFFECTIVE DATE.—(1) Except as provided in this subsection, the amendment made by subsection (a) shall be effective as if included in the enactment of section 4354 of the Omnibus Budget Reconciliation Act of 1990.

(2)(A) Clause (vi) of section 1882(d)(3)(A) of the Social Security Act, as added by subsection (a), shall only apply to individuals applying for—

(i) a health insurance policy described in section 1882(d)(3)(A)(iv) of such Act (as added by subsection (a)), after the date of the enactment of this Act, or

(ii) another health insurance policy after the end of the 30-day period beginning on the date of the enactment of this Act.

(B) A seller or issuer of a health insurance policy may substitute, for the disclosure statement described in clause (vii) of such section, the statement specified under section 1882(d)(3)(D) of the Social Security Act (as in effect before the date of the enactment of this Act), without the revision specified in such clause.

TITLE III—TAX-RELATED HEALTH PROVISIONS

SEC. 300. AMENDMENT OF 1986 CODE.

Except as otherwise expressly provided, whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Internal Revenue Code of 1986.

Subtitle A—Medical Savings Accounts

SEC. 301. MEDICAL SAVINGS ACCOUNTS.

<< 26 USCA § 220 >>

<< 26 USCA § 221 >>

(a) IN GENERAL.—Part VII of subchapter B of chapter 1 (relating to additional itemized deductions for individuals) is amended by redesignating section 220 as section 221 and by inserting after section 219 the following new section:

<< 26 USCA § 220 >>

“SEC. 220. MEDICAL SAVINGS ACCOUNTS.

“(a) DEDUCTION ALLOWED.—In the case of an individual who is an eligible individual for any month during the taxable year, there shall be allowed as a deduction for the taxable year an amount equal to the aggregate amount paid in cash during such taxable year by such individual to a medical savings account of such individual.

“(b) LIMITATIONS.—

“(1) IN GENERAL.—The amount allowable as a deduction under subsection (a) to an individual for the taxable year shall not exceed the sum of the monthly limitations for months during such taxable year that the individual is an eligible individual.

“(2) MONTHLY LIMITATION.—The monthly limitation for any month is the amount equal to $\frac{1}{12}$ of—

“(A) in the case of an individual who has self-only coverage under the high deductible health plan as of the first day of such month, 65 percent of the annual deductible under such coverage, and

“(B) in the case of an individual who has family coverage under the high deductible health plan as of the first day of such month, 75 percent of the annual deductible under such coverage.

“(3) SPECIAL RULE FOR MARRIED INDIVIDUALS.—In the case of individuals who are married to each other, if either spouse has family coverage—

“(A) both spouses shall be treated as having only such family coverage (and if such spouses each have family coverage under different plans, as having the family coverage with the lowest annual deductible), and

“(B) the limitation under paragraph (1) (after the application of subparagraph (A) of this paragraph) shall be divided equally between them unless they agree on a different division.

“(4) DEDUCTION NOT TO EXCEED COMPENSATION.—

“(A) EMPLOYEES.—The deduction allowed under subsection (a) for contributions as an eligible individual described in subclause (I) of subsection (c)(1)(A)(iii) shall not exceed such individual's wages, salaries, tips, and other employee compensation which are attributable to such individual's employment by the employer referred to in such subclause.

“(B) SELF-EMPLOYED INDIVIDUALS.—The deduction allowed under subsection (a) for contributions as an eligible individual described in subclause (II) of subsection (c)(1)(A)(iii) shall not exceed such individual's earned income (as defined in section 401(c)(1)) derived by the taxpayer from the trade or business with respect to which the high deductible health plan is established.

“(C) COMMUNITY PROPERTY LAWS NOT TO APPLY.—The limitations under this paragraph shall be determined without regard to community property laws.

“(5) COORDINATION WITH EXCLUSION FOR EMPLOYER CONTRIBUTIONS.—No deduction shall be allowed under this section for any amount paid for any taxable year to a medical savings account of an individual if—

“(A) any amount is contributed to any medical savings account of such individual for such year which is excludable from gross income under section 106(b), or

“(B) if such individual's spouse is covered under the high deductible health plan covering such individual, any amount is contributed for such year to any medical savings account of such spouse which is so excludable.

“(6) DENIAL OF DEDUCTION TO DEPENDENTS.—No deduction shall be allowed under this section to any individual with respect to whom a deduction under section 151 is allowable to another taxpayer for a taxable year beginning in the calendar year in which such individual's taxable year begins.

“(c) DEFINITIONS.—For purposes of this section—

“(1) ELIGIBLE INDIVIDUAL.—

“(A) IN GENERAL.—The term ‘eligible individual’ means, with respect to any month, any individual if—

“(i) such individual is covered under a high deductible health plan as of the 1st day of such month,

“(ii) such individual is not, while covered under a high deductible health plan, covered under any health plan—

“(I) which is not a high deductible health plan, and

“(II) which provides coverage for any benefit which is covered under the high deductible health plan, and

“(iii)(I) the high deductible health plan covering such individual is established and maintained by the employer of such individual or of the spouse of such individual and such employer is a small employer, or

“(II) such individual is an employee (within the meaning of section 401(c)(1)) or the spouse of such an employee and the high deductible health plan covering such individual is not established or maintained by any employer of such individual or spouse.

“(B) CERTAIN COVERAGE DISREGARDED.—Subparagraph (A)(ii) shall be applied without regard to—

“(i) coverage for any benefit provided by permitted insurance, and

“(ii) coverage (whether through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

“(C) CONTINUED ELIGIBILITY OF EMPLOYEE AND SPOUSE ESTABLISHING MEDICAL SAVINGS ACCOUNTS.—If, while an employer is a small employer—

“(i) any amount is contributed to a medical savings account of an individual who is an employee of such employer or the spouse of such an employee, and

“(ii) such amount is excludable from gross income under section 106(b) or allowable as a deduction under this section,

such individual shall not cease to meet the requirement of subparagraph (A)(iii)(I) by reason of such employer ceasing to be a small employer so long as such employee continues to be an employee of such employer.

“(D) LIMITATIONS ON ELIGIBILITY.—

“For limitations on number of taxpayers who are eligible to have medical savings accounts, see subsection (i).

“(2) HIGH DEDUCTIBLE HEALTH PLAN.—

“(A) IN GENERAL.—The term ‘high deductible health plan’ means a health plan—

“(i) in the case of self-only coverage, which has an annual deductible which is not less than \$1,500 and not more than \$2,250,

“(ii) in the case of family coverage, which has an annual deductible which is not less than \$3,000 and not more than \$4,500, and

“(iii) the annual out-of-pocket expenses required to be paid under the plan (other than for premiums) for covered benefits does not exceed—

“(I) \$3,000 for self-only coverage, and

“(II) \$5,500 for family coverage.

“(B) SPECIAL RULES.—

“(i) EXCLUSION OF CERTAIN PLANS.—Such term does not include a health plan if substantially all of its coverage is coverage described in paragraph (1)(B).

“(ii) SAFE HARBOR FOR ABSENCE OF PREVENTIVE CARE DEDUCTIBLE.—A plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care if the absence of a deductible for such care is required by State law.

“(3) PERMITTED INSURANCE.—The term ‘permitted insurance’ means—

“(A) Medicare supplemental insurance,

“(B) insurance if substantially all of the coverage provided under such insurance relates to—

“(i) liabilities incurred under workers' compensation laws,

“(ii) tort liabilities,

“(iii) liabilities relating to ownership or use of property, or

“(iv) such other similar liabilities as the Secretary may specify by regulations,

“(C) insurance for a specified disease or illness, and

“(D) insurance paying a fixed amount per day (or other period) of hospitalization.

“(4) SMALL EMPLOYER.—

“(A) IN GENERAL.—The term ‘small employer’ means, with respect to any calendar year, any employer if such employer employed an average of 50 or fewer employees on business days during either of the 2 preceding calendar years. For purposes of the preceding sentence, a preceding calendar year may be taken into account only if the employer was in existence throughout such year.

“(B) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence throughout the 1st preceding calendar year, the determination under subparagraph (A) shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

“(C) CERTAIN GROWING EMPLOYERS RETAIN TREATMENT AS SMALL EMPLOYER.—The term ‘small employer’ includes, with respect to any calendar year, any employer if—

“(i) such employer met the requirement of subparagraph (A) (determined without regard to subparagraph (B)) for any preceding calendar year after 1996,

“(ii) any amount was contributed to the medical savings account of any employee of such employer with respect to coverage of such employee under a high deductible health plan of such employer during such preceding calendar year and such amount was excludable from gross income under section 106(b) or allowable as a deduction under this section, and

“(iii) such employer employed an average of 200 or fewer employees on business days during each preceding calendar year after 1996.

“(D) SPECIAL RULES.—

“(i) CONTROLLED GROUPS.—For purposes of this paragraph, all persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 shall be treated as 1 employer.

“(ii) PREDECESSORS.—Any reference in this paragraph to an employer shall include a reference to any predecessor of such employer.

“(5) FAMILY COVERAGE.—The term ‘family coverage’ means any coverage other than self-only coverage.

“(d) MEDICAL SAVINGS ACCOUNT.—For purposes of this section—

“(1) MEDICAL SAVINGS ACCOUNT.—The term ‘medical savings account’ means a trust created or organized in the United States exclusively for the purpose of paying the qualified medical expenses of the account holder, but only if the written governing instrument creating the trust meets the following requirements:

“(A) Except in the case of a rollover contribution described in subsection (f)(5), no contribution will be accepted—

“(i) unless it is in cash, or

“(ii) to the extent such contribution, when added to previous contributions to the trust for the calendar year, exceeds 75 percent of the highest annual limit deductible permitted under subsection (c)(2)(A)(ii) for such calendar year.

“(B) The trustee is a bank (as defined in section 408(n)), an insurance company (as defined in section 816), or another person who demonstrates to the satisfaction of the Secretary that the manner in which such person will administer the trust will be consistent with the requirements of this section.

“(C) No part of the trust assets will be invested in life insurance contracts.

“(D) The assets of the trust will not be commingled with other property except in a common trust fund or common investment fund.

“(E) The interest of an individual in the balance in his account is nonforfeitable.

“(2) QUALIFIED MEDICAL EXPENSES.—

“(A) IN GENERAL.—The term ‘qualified medical expenses’ means, with respect to an account holder, amounts paid by such holder for medical care (as defined in section 213(d)) for such individual, the spouse of such individual, and any dependent (as defined in section 152) of such individual, but only to the extent such amounts are not compensated for by insurance or otherwise.

“(B) HEALTH INSURANCE MAY NOT BE PURCHASED FROM ACCOUNT.—

“(i) IN GENERAL.—Subparagraph (A) shall not apply to any payment for insurance.

“(ii) EXCEPTIONS.—Clause (i) shall not apply to any expense for coverage under—

“(I) a health plan during any period of continuation coverage required under any Federal law,

“(II) a qualified long-term care insurance contract (as defined in section 7702B(b)), or

“(III) a health plan during a period in which the individual is receiving unemployment compensation under any Federal or State law.

“(C) MEDICAL EXPENSES OF INDIVIDUALS WHO ARE NOT ELIGIBLE INDIVIDUALS.—Subparagraph (A) shall apply to an amount paid by an account holder for medical care of an individual who is not an eligible individual for the month in which the expense for such care is incurred only if no amount is contributed (other than a rollover contribution) to any medical savings account of such account holder for the taxable year which includes such month. This subparagraph shall not apply to any expense for coverage described in subclause (I) or (III) of subparagraph (B)(ii).

“(3) ACCOUNT HOLDER.—The term ‘account holder’ means the individual on whose behalf the medical savings account was established.

“(4) CERTAIN RULES TO APPLY.—Rules similar to the following rules shall apply for purposes of this section:

“(A) Section 219(d)(2) (relating to no deduction for rollovers).

“(B) Section 219(f)(3) (relating to time when contributions deemed made).

“(C) Except as provided in section 106(b), section 219(f)(5) (relating to employer payments).

“(D) Section 408(g) (relating to community property laws).

“(E) Section 408(h) (relating to custodial accounts).

“(e) TAX TREATMENT OF ACCOUNTS.—

“(1) IN GENERAL.—A medical savings account is exempt from taxation under this subtitle unless such account has ceased to be a medical savings account. Notwithstanding the preceding sentence, any such account is subject to the taxes imposed by section 511 (relating to imposition of tax on unrelated business income of charitable, etc. organizations).

“(2) ACCOUNT TERMINATIONS.—Rules similar to the rules of paragraphs (2) and (4) of section 408(e) shall apply to medical savings accounts, and any amount treated as distributed under such rules shall be treated as not used to pay qualified medical expenses.

“(f) TAX TREATMENT OF DISTRIBUTIONS.—

“(1) AMOUNTS USED FOR QUALIFIED MEDICAL EXPENSES.—Any amount paid or distributed out of a medical savings account which is used exclusively to pay qualified medical expenses of any account holder shall not be includible in gross income.

“(2) INCLUSION OF AMOUNTS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—Any amount paid or distributed out of a medical savings account which is not used exclusively to pay the qualified medical expenses of the account holder shall be included in the gross income of such holder.

“(3) EXCESS CONTRIBUTIONS RETURNED BEFORE DUE DATE OF RETURN.—

“(A) IN GENERAL.—If any excess contribution is contributed for a taxable year to any medical savings account of an individual, paragraph (2) shall not apply to distributions from the medical savings accounts of such individual (to the extent such distributions do not exceed the aggregate excess contributions to all such accounts of such individual for such year) if—

“(i) such distribution is received by the individual on or before the last day prescribed by law (including extensions of time) for filing such individual's return for such taxable year, and

“(ii) such distribution is accompanied by the amount of net income attributable to such excess contribution.

Any net income described in clause (ii) shall be included in the gross income of the individual for the taxable year in which it is received.

“(B) EXCESS CONTRIBUTION.—For purposes of subparagraph (A), the term ‘excess contribution’ means any contribution (other than a rollover contribution) which is neither excludable from gross income under section 106(b) nor deductible under this section.

“(4) ADDITIONAL TAX ON DISTRIBUTIONS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—

“(A) IN GENERAL.—The tax imposed by this chapter on the account holder for any taxable year in which there is a payment or distribution from a medical savings account of such holder which is includible in gross income under paragraph (2) shall be increased by 15 percent of the amount which is so includible.

“(B) EXCEPTION FOR DISABILITY OR DEATH.—Subparagraph (A) shall not apply if the payment or distribution is made after the account holder becomes disabled within the meaning of section 72(m)(7) or dies.

“(C) EXCEPTION FOR DISTRIBUTIONS AFTER MEDICARE ELIGIBILITY.—Subparagraph (A) shall not apply to any payment or distribution after the date on which the account holder attains the age specified in section 1811 of the Social Security Act.

“(5) ROLLOVER CONTRIBUTION.—An amount is described in this paragraph as a rollover contribution if it meets the requirements of subparagraphs (A) and (B).

“(A) IN GENERAL.—Paragraph (2) shall not apply to any amount paid or distributed from a medical savings account to the account holder to the extent the amount received is paid into a medical savings account for the benefit of such holder not later than the 60th day after the day on which the holder receives the payment or distribution.

“(B) LIMITATION.—This paragraph shall not apply to any amount described in subparagraph (A) received by an individual from a medical savings account if, at any time during the 1-year period ending on the day of such receipt, such individual received any other amount described in subparagraph (A) from a medical savings account which was not includible in the individual's gross income because of the application of this paragraph.

“(6) COORDINATION WITH MEDICAL EXPENSE DEDUCTION.—For purposes of determining the amount of the deduction under section 213, any payment or distribution out of a medical savings account for qualified medical expenses shall not be treated as an expense paid for medical care.

“(7) TRANSFER OF ACCOUNT INCIDENT TO DIVORCE.—The transfer of an individual's interest in a medical savings account to an individual's spouse or former spouse under a divorce or separation instrument described in subparagraph (A) of section 71(b)(2) shall not be considered a taxable transfer made by such individual notwithstanding any other provision of this subtitle, and such interest shall, after such transfer, be treated as a medical savings account with respect to which such spouse is the account holder.

“(8) TREATMENT AFTER DEATH OF ACCOUNT HOLDER.—

“(A) TREATMENT IF DESIGNATED BENEFICIARY IS SPOUSE.—If the account holder's surviving spouse acquires such holder's interest in a medical savings account by reason of being the designated beneficiary of such account at the death of the account holder, such medical savings account shall be treated as if the spouse were the account holder.

“(B) OTHER CASES.—

“(i) IN GENERAL.—If, by reason of the death of the account holder, any person acquires the account holder's interest in a medical savings account in a case to which subparagraph (A) does not apply—

“(I) such account shall cease to be a medical savings account as of the date of death, and

“(II) an amount equal to the fair market value of the assets in such account on such date shall be includible if such person is not the estate of such holder, in such person's gross income for the taxable year which includes such date, or if such person is the estate of such holder, in such holder's gross income for the last taxable year of such holder.

“(ii) SPECIAL RULES.—

“(I) REDUCTION OF INCLUSION FOR PRE-DEATH EXPENSES.—The amount includible in gross income under clause (i) by any person (other than the estate) shall be reduced by the amount of qualified medical expenses which were incurred by the decedent before the date of the decedent's death and paid by such person within 1 year after such date.

“(II) DEDUCTION FOR ESTATE TAXES.—An appropriate deduction shall be allowed under section 691(c) to any person (other than the decedent or the decedent's spouse) with respect to amounts included in gross income under clause (i) by such person.

“(g) COST-OF-LIVING ADJUSTMENT.—In the case of any taxable year beginning in a calendar year after 1998, each dollar amount in subsection (c)(2) shall be increased by an amount equal to—

“(1) such dollar amount, multiplied by

“(2) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which such taxable year begins by substituting ‘calendar year 1997’ for ‘calendar year 1992’ in subparagraph (B) thereof.

If any increase under the preceding sentence is not a multiple of \$50, such increase shall be rounded to the nearest multiple of \$50.

“(h) REPORTS.—The Secretary may require the trustee of a medical savings account to make such reports regarding such account to the Secretary and to the account holder with respect to contributions, distributions, and such other matters as the Secretary determines appropriate. The reports required by this subsection shall be filed at such time and in such manner and furnished to such individuals at such time and in such manner as may be required by the Secretary.

“(i) LIMITATION ON NUMBER OF TAXPAYERS HAVING MEDICAL SAVINGS ACCOUNTS.—

“(1) IN GENERAL.—Except as provided in paragraph (5), no individual shall be treated as an eligible individual for any taxable year beginning after the cut-off year unless—

“(A) such individual was an active MSA participant for any taxable year ending on or before the close of the cut-off year, or

“(B) such individual first became an active MSA participant for a taxable year ending after the cut-off year by reason of coverage under a high deductible health plan of an MSA-participating employer.

“(2) CUT-OFF YEAR.—For purposes of paragraph (1), the term ‘cut-off year’ means the earlier of—

“(A) calendar year 2000, or

“(B) the first calendar year before 2000 for which the Secretary determines under subsection (j) that the numerical limitation for such year has been exceeded.

“(3) ACTIVE MSA PARTICIPANT.—For purposes of this subsection—

“(A) IN GENERAL.—The term ‘active MSA participant’ means, with respect to any taxable year, any individual who is the account holder of any medical savings account into which any contribution was made which was excludable from gross income under section 106(b), or allowable as a deduction under this section, for such taxable year.

“(B) SPECIAL RULE FOR CUT-OFF YEARS BEFORE 2000.—In the case of a cut-off year before 2000—

“(i) an individual shall not be treated as an eligible individual for any month of such year or an active MSA participant under paragraph (1)(A) unless such individual is, on or before the cut-off date, covered under a high deductible health plan, and

“(ii) an employer shall not be treated as an MSA-participating employer unless the employer, on or before the cut-off date, offered coverage under a high deductible health plan to any employee.

“(C) CUT-OFF DATE.—For purposes of subparagraph (B)—

“(i) IN GENERAL.—Except as otherwise provided in this subparagraph, the cut-off date is October 1 of the cut-off year.

“(ii) EMPLOYEES WITH ENROLLMENT PERIODS AFTER OCTOBER 1.—In the case of an individual described in subclause (I) of subsection (c)(1)(A)(iii), if the regularly scheduled enrollment period for health plans of the individual's employer occurs during the last 3 months of the cut-off year, the cut-off date is December 31 of the cut-off year.

“(iii) SELF-EMPLOYED INDIVIDUALS.—In the case of an individual described in subclause (II) of subsection (c)(1)(A)(iii), the cut-off date is November 1 of the cut-off year.

“(iv) SPECIAL RULES FOR 1997.—If 1997 is a cut-off year by reason of subsection (j)(1)(A)—

“(I) each of the cut-off dates under clauses (i) and (iii) shall be 1 month earlier than the date determined without regard to this clause, and

“(II) clause (ii) shall be applied by substituting ‘4 months’ for ‘3 months’.

“(4) MSA-PARTICIPATING EMPLOYER.—For purposes of this subsection, the term ‘MSA-participating employer’ means any small employer if—

“(A) such employer made any contribution to the medical savings account of any employee during the cut-off year or any preceding calendar year which was excludable from gross income under section 106(b), or

“(B) at least 20 percent of the employees of such employer who are eligible individuals for any month of the cut-off year by reason of coverage under a high deductible health plan of such employer each made a contribution of at least \$100 to their medical savings accounts for any taxable year ending with or within the cut-off year which was allowable as a deduction under this section.

“(5) ADDITIONAL ELIGIBILITY AFTER CUT-OFF YEAR.—If the Secretary determines under subsection (j)(2)(A) that the numerical limit for the calendar year following a cut-off year described in paragraph (2)(B) has not been exceeded—

“(A) this subsection shall not apply to any otherwise eligible individual who is covered under a high deductible health plan during the first 6 months of the second calendar year following the cut-off year (and such individual shall be treated as an active MSA participant for purposes of this subsection if a contribution is made to any medical savings account with respect to such coverage), and

“(B) any employer who offers coverage under a high deductible health plan to any employee during such 6-month period shall be treated as an MSA-participating employer for purposes of this subsection if the requirements of paragraph (4) are met with respect to such coverage.

For purposes of this paragraph, subsection (j)(2)(A) shall be applied for 1998 by substituting ‘750,000’ for ‘600,000’.

“(j) DETERMINATION OF WHETHER NUMERICAL LIMITS ARE EXCEEDED.—

“(1) DETERMINATION OF WHETHER LIMIT EXCEEDED FOR 1997.—The numerical limitation for 1997 is exceeded if, based on the reports required under paragraph (4), the number of medical savings accounts established as of—

“(A) April 30, 1997, exceeds 375,000, or

“(B) June 30, 1997, exceeds 525,000.

“(2) DETERMINATION OF WHETHER LIMIT EXCEEDED FOR 1998 OR 1999.—

“(A) IN GENERAL.—The numerical limitation for 1998 or 1999 is exceeded if the sum of—

“(i) the number of MSA returns filed on or before April 15 of such calendar year for taxable years ending with or within the preceding calendar year, plus

“(ii) the Secretary's estimate (determined on the basis of the returns described in clause (i)) of the number of MSA returns for such taxable years which will be filed after such date,

exceeds 600,000 (750,000 in the case of 1999). For purposes of the preceding sentence, the term ‘MSA return’ means any return on which any exclusion is claimed under section 106(b) or any deduction is claimed under this section.

“(B) ALTERNATIVE COMPUTATION OF LIMITATION.—The numerical limitation for 1998 or 1999 is also exceeded if the sum of—

“(i) 90 percent of the sum determined under subparagraph (A) for such calendar year, plus

“(ii) the product of 2.5 and the number of medical savings accounts established during the portion of such year preceding July 1 (based on the reports required under paragraph (4)) for taxable years beginning in such year,

exceeds 750,000.

“(3) PREVIOUSLY UNINSURED INDIVIDUALS NOT INCLUDED IN DETERMINATION.—

“(A) IN GENERAL.—The determination of whether any calendar year is a cut-off year shall be made by not counting the medical savings account of any previously uninsured individual.

“(B) PREVIOUSLY UNINSURED INDIVIDUAL.—For purposes of this subsection, the term ‘previously uninsured individual’ means, with respect to any medical savings account, any individual who had no health plan coverage (other than coverage referred to in subsection (c)(1)(B)) at any time during the 6-month period before the date such individual’s coverage under the high deductible health plan commences.

“(4) REPORTING BY MSA TRUSTEES.—

“(A) IN GENERAL.—Not later than August 1 of 1997, 1998, and 1999, each person who is the trustee of a medical savings account established before July 1 of such calendar year shall make a report to the Secretary (in such form and manner as the Secretary shall specify) which specifies—

“(i) the number of medical savings accounts established before such July 1 (for taxable years beginning in such calendar year) of which such person is the trustee,

“(ii) the name and TIN of the account holder of each such account, and

“(iii) the number of such accounts which are accounts of previously uninsured individuals.

“(B) ADDITIONAL REPORT FOR 1997.—Not later than June 1, 1997, each person who is the trustee of a medical savings account established before May 1, 1997, shall make an additional report described in subparagraph (A) but only with respect to accounts established before May 1, 1997.

“(C) PENALTY FOR FAILURE TO FILE REPORT.—The penalty provided in section 6693(a) shall apply to any report required by this paragraph, except that—

“(i) such section shall be applied by substituting ‘\$25’ for ‘\$50’, and

“(ii) the maximum penalty imposed on any trustee shall not exceed \$5,000.

“(D) AGGREGATION OF ACCOUNTS.—To the extent practicable, in determining the number of medical savings accounts on the basis of the reports under this paragraph, all medical savings accounts of an individual shall be treated as 1 account and all accounts of individuals who are married to each other shall be treated as 1 account.

“(5) DATE OF MAKING DETERMINATIONS.—Any determination under this subsection that a calendar year is a cut-off year shall be made by the Secretary and shall be published not later than October 1 of such year.”.

<< 26 USCA § 62 >>

(b) DEDUCTION ALLOWED WHETHER OR NOT INDIVIDUAL ITEMIZES OTHER DEDUCTIONS.—Subsection (a) of section 62 is amended by inserting after paragraph (15) the following new paragraph:

“(16) MEDICAL SAVINGS ACCOUNTS.—The deduction allowed by section 220.”.

(c) EXCLUSIONS FOR EMPLOYER CONTRIBUTIONS TO MEDICAL SAVINGS ACCOUNTS.—

<< 26 USCA § 106 >>

(1) EXCLUSION FROM INCOME TAX.—The text of section 106 (relating to contributions by employer to accident and health plans) is amended to read as follows:

“(a) GENERAL RULE.—Except as otherwise provided in this section, gross income of an employee does not include employer-provided coverage under an accident or health plan.

“(b) CONTRIBUTIONS TO MEDICAL SAVINGS ACCOUNTS.—

“(1) IN GENERAL.—In the case of an employee who is an eligible individual, amounts contributed by such employee’s employer to any medical savings account of such employee shall be treated as employer-provided coverage for medical expenses under an accident or health plan to the extent such amounts do not exceed the limitation under section 220(b)(1) (determined without regard to this subsection) which is applicable to such employee for such taxable year.

“(2) NO CONSTRUCTIVE RECEIPT.—No amount shall be included in the gross income of any employee solely because the employee may choose between the contributions referred to in paragraph (1) and employer contributions to another health plan of the employer.

“(3) SPECIAL RULE FOR DEDUCTION OF EMPLOYER CONTRIBUTIONS.—Any employer contribution to a medical savings account, if otherwise allowable as a deduction under this chapter, shall be allowed only for the taxable year in which paid.

“(4) EMPLOYER MSA CONTRIBUTIONS REQUIRED TO BE SHOWN ON RETURN.—Every individual required to file a return under section 6012 for the taxable year shall include on such return the aggregate amount contributed by employers to the medical savings accounts of such individual or such individual's spouse for such taxable year.

“(5) MSA CONTRIBUTIONS NOT PART OF COBRA COVERAGE.—Paragraph (1) shall not apply for purposes of section 4980B.

“(6) DEFINITIONS.—For purposes of this subsection, the terms ‘eligible individual’ and ‘medical savings account’ have the respective meanings given to such terms by section 220.

“(7) CROSS REFERENCE.—

“For penalty on failure by employer to make comparable contributions to the medical savings accounts of comparable employees, see section 4980E.”.

(2) EXCLUSION FROM EMPLOYMENT TAXES.—

<< 26 USCA § 3231 >>

(A) RAILROAD RETIREMENT TAX.—Subsection (e) of section 3231 is amended by adding at the end the following new paragraph:

“(10) MEDICAL SAVINGS ACCOUNT CONTRIBUTIONS.—The term ‘compensation’ shall not include any payment made to or for the benefit of an employee if at the time of such payment it is reasonable to believe that the employee will be able to exclude such payment from income under section 106(b).”.

<< 26 USCA § 3306 >>

(B) UNEMPLOYMENT TAX.—Subsection (b) of section 3306 is amended by striking “or” at the end of paragraph (15), by striking the period at the end of paragraph (16) and inserting “; or”, and by inserting after paragraph (16) the following new paragraph:

“(17) any payment made to or for the benefit of an employee if at the time of such payment it is reasonable to believe that the employee will be able to exclude such payment from income under section 106(b).”.

<< 26 USCA § 3401 >>

(C) WITHHOLDING TAX.—Subsection (a) of section 3401 is amended by striking “or” at the end of paragraph (19), by striking the period at the end of paragraph (20) and inserting “; or”, and by inserting after paragraph (20) the following new paragraph:

“(21) any payment made to or for the benefit of an employee if at the time of such payment it is reasonable to believe that the employee will be able to exclude such payment from income under section 106(b).”.

<< 26 USCA § 6051 >>

(3) EMPLOYER CONTRIBUTIONS REQUIRED TO BE SHOWN ON W-2.—Subsection (a) of section 6051 is amended by striking “and” at the end of paragraph (9), by striking the period at the end of paragraph (10) and inserting “, and”, and by inserting after paragraph (10) the following new paragraph:

“(11) the amount contributed to any medical savings account (as defined in section 220(d)) of such employee or such employee's spouse.”.

(4) PENALTY FOR FAILURE OF EMPLOYER TO MAKE COMPARABLE MSA CONTRIBUTIONS.—

<< 26 USCA § 4980E >>

(A) IN GENERAL.—Chapter 43 is amended by adding after section 4980D the following new section:

“SEC. 4980E. FAILURE OF EMPLOYER TO MAKE COMPARABLE MEDICAL SAVINGS ACCOUNT CONTRIBUTIONS.

“(a) GENERAL RULE.—In the case of an employer who makes a contribution to the medical savings account of any employee with respect to coverage under a high deductible health plan of the employer during a calendar year, there is hereby imposed a tax on the failure of such employer to meet the requirements of subsection (d) for such calendar year.

“(b) AMOUNT OF TAX.—The amount of the tax imposed by subsection (a) on any failure for any calendar year is the amount equal to 35 percent of the aggregate amount contributed by the employer to medical savings accounts of employees for taxable years of such employees ending with or within such calendar year.

“(c) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the tax imposed by subsection (a) to the extent that the payment of such tax would be excessive relative to the failure involved.

“(d) EMPLOYER REQUIRED TO MAKE COMPARABLE MSA CONTRIBUTIONS FOR ALL PARTICIPATING EMPLOYEES.—

“(1) IN GENERAL.—An employer meets the requirements of this subsection for any calendar year if the employer makes available comparable contributions to the medical savings accounts of all comparable participating employees for each coverage period during such calendar year.

“(2) COMPARABLE CONTRIBUTIONS.—

“(A) IN GENERAL.—For purposes of paragraph (1), the term ‘comparable contributions’ means contributions—

“(i) which are the same amount, or

“(ii) which are the same percentage of the annual deductible limit under the high deductible health plan covering the employees.

“(B) PART-YEAR EMPLOYEES.—In the case of an employee who is employed by the employer for only a portion of the calendar year, a contribution to the medical savings account of such employee shall be treated as comparable if it is an amount which bears the same ratio to the comparable amount (determined without regard to this subparagraph) as such portion bears to the entire calendar year.

“(3) COMPARABLE PARTICIPATING EMPLOYEES.—For purposes of paragraph (1), the term ‘comparable participating employees’ means all employees—

“(A) who are eligible individuals covered under any high deductible health plan of the employer, and

“(B) who have the same category of coverage.

For purposes of subparagraph (B), the categories of coverage are self-only and family coverage.

“(4) PART-TIME EMPLOYEES.—

“(A) IN GENERAL.—Paragraph (3) shall be applied separately with respect to part-time employees and other employees.

“(B) PART-TIME EMPLOYEE.—For purposes of subparagraph (A), the term ‘part-time employee’ means any employee who is customarily employed for fewer than 30 hours per week.

“(e) CONTROLLED GROUPS.—For purposes of this section, all persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 shall be treated as 1 employer.

“(f) DEFINITIONS.—Terms used in this section which are also used in section 220 have the respective meanings given such terms in section 220.”.

<< 26 USCA Ch. 43 >>

(B) CLERICAL AMENDMENT.—The table of sections for chapter 43 is amended by adding after the item relating to section 4980D the following new item:

“Sec. 4980E. Failure of employer to make comparable medical savings account contributions.”.

<< 26 USCA § 125 >>

(d) MEDICAL SAVINGS ACCOUNT CONTRIBUTIONS NOT AVAILABLE UNDER CAFETERIA PLANS.—Subsection (f) of section 125 of such Code is amended by inserting “106(b),” before “117”.

<< 26 USCA § 4973 >>

(e) TAX ON EXCESS CONTRIBUTIONS.—Section 4973 (relating to tax on excess contributions to individual retirement accounts, certain section 403(b) contracts, and certain individual retirement annuities) is amended—

(1) by inserting “MEDICAL SAVINGS ACCOUNTS,” after “ACCOUNTS,” in the heading of such section,

(2) by striking “or” at the end of paragraph (1) of subsection (a),

(3) by redesignating paragraph (2) of subsection (a) as paragraph (3) and by inserting after paragraph (1) the following:

“(2) a medical savings account (within the meaning of section 220(d)), or”, and

(4) by adding at the end the following new subsection:

“(d) EXCESS CONTRIBUTIONS TO MEDICAL SAVINGS ACCOUNTS.—For purposes of this section, in the case of medical savings accounts (within the meaning of section 220(d)), the term ‘excess contributions’ means the sum of—

“(1) the aggregate amount contributed for the taxable year to the accounts (other than rollover contributions described in section 220(f)(5)) which is neither excludable from gross income under section 106(b) nor allowable as a deduction under section 220 for such year, and

“(2) the amount determined under this subsection for the preceding taxable year, reduced by the sum of—

“(A) the distributions out of the accounts which were included in gross income under section 220(f)(2), and

“(B) the excess (if any) of—

“(i) the maximum amount allowable as a deduction under section 220(b)(1) (determined without regard to section 106(b)) for the taxable year, over

“(ii) the amount contributed to the accounts for the taxable year.

For purposes of this subsection, any contribution which is distributed out of the medical savings account in a distribution to which section 220(f)(3) applies shall be treated as an amount not contributed.”.

<< 26 USCA § 4975 >>

(f) TAX ON PROHIBITED TRANSACTIONS.—

(1) Section 4975 (relating to tax on prohibited transactions) is amended by adding at the end of subsection (c) the following new paragraph:

“(4) SPECIAL RULE FOR MEDICAL SAVINGS ACCOUNTS.—An individual for whose benefit a medical savings account (within the meaning of section 220(d)) is established shall be exempt from the tax imposed by this section with respect to any transaction concerning such account (which would otherwise be taxable under this section) if, with respect to such transaction, the account ceases to be a medical savings account by reason of the application of section 220(e)(2) to such account.”.

(2) Paragraph (1) of section 4975(e) is amended to read as follows:

“(1) PLAN.—For purposes of this section, the term ‘plan’ means—

“(A) a trust described in section 401(a) which forms a part of a plan, or a plan described in section 403(a), which trust or plan is exempt from tax under section 501(a),

“(B) an individual retirement account described in section 408(a),

“(C) an individual retirement annuity described in section 408(b),

“(D) a medical savings account described in section 220(d), or

“(E) a trust, plan, account, or annuity which, at any time, has been determined by the Secretary to be described in any preceding subparagraph of this paragraph.”.

<< 26 USCA § 6693 >>

(g) FAILURE TO PROVIDE REPORTS ON MEDICAL SAVINGS ACCOUNTS.—

(1) Subsection (a) of section 6693 (relating to failure to provide reports on individual retirement accounts or annuities) is amended to read as follows:

“(a) REPORTS.—

“(1) IN GENERAL.—If a person required to file a report under a provision referred to in paragraph (2) fails to file such report at the time and in the manner required by such provision, such person shall pay a penalty of \$50 for each failure unless it is shown that such failure is due to reasonable cause.

“(2) PROVISIONS.—The provisions referred to in this paragraph are—

“(A) subsections (i) and (l) of section 408 (relating to individual retirement plans), and

“(B) section 220(h) (relating to medical savings accounts).”.

<< 26 USCA § 848 >>

(h) EXCEPTION FROM CAPITALIZATION OF POLICY ACQUISITION EXPENSES.—Subparagraph (B) of section 848(e)(1) (defining specified insurance contract) is amended by striking “and” at the end of clause (ii), by striking the period at the end of clause (iii) and inserting “, and”, and by adding at the end the following new clause:

“(iv) any contract which is a medical savings account (as defined in section 220(d)).”.

<< 26 USCA Ch. 1 >>

(i) CLERICAL AMENDMENT.—The table of sections for part VII of subchapter B of chapter 1 is amended by striking the last item and inserting the following:

“Sec. 220. Medical savings accounts.

“Sec. 221. Cross reference.”.

<< 26 USCA §§ 62 NOTE, 106 nt, 125 nt, 220 nt, 848 nt, 3231 nt, 3306 nt, 3401 nt, 4973 nt, 4975 nt, 6051 nt, 6693 nt >>

<< 26 USCA § 4980E nt >>

(j) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1996.

<< 26 USCA § 220 NOTE >>

(k) MONITORING OF PARTICIPATION IN MEDICAL SAVINGS ACCOUNTS.—The Secretary of the Treasury or his delegate shall—

(1) during 1997, 1998, 1999, and 2000, regularly evaluate the number of individuals who are maintaining medical savings accounts and the reduction in revenues to the United States by reason of such accounts, and

(2) provide such reports of such evaluations to Congress as such Secretary determines appropriate.

<< 26 USCA § 220 NOTE >>

(l) STUDY OF EFFECTS OF MEDICAL SAVINGS ACCOUNTS ON SMALL GROUP MARKET.—The Comptroller General of the United States shall enter into a contract with an organization with expertise in health economics, health insurance markets, and actuarial science to conduct a comprehensive study regarding the effects of medical savings accounts in the small group market on—

(1) selection, including adverse selection,

(2) health costs, including any impact on premiums of individuals with comprehensive coverage,

(3) use of preventive care,

(4) consumer choice,

(5) the scope of coverage of high deductible plans purchased in conjunction with such accounts, and

(6) other relevant items.

A report on the results of the study conducted under this subsection shall be submitted to the Congress no later than January 1, 1999.

Subtitle B—Increase in Deduction for Health Insurance Costs of Self-Employed Individuals

SEC. 311. INCREASE IN DEDUCTION FOR HEALTH INSURANCE COSTS OF SELF-EMPLOYED INDIVIDUALS.

<< 26 USCA § 162 >>

(a) IN GENERAL.—Paragraph (1) of section 162(l) is amended to read as follows:

“(1) ALLOWANCE OF DEDUCTION.—

“(A) IN GENERAL.—In the case of an individual who is an employee within the meaning of section 401(c)(1), there shall be allowed as a deduction under this section an amount equal to the applicable percentage of the amount paid during the taxable year for insurance which constitutes medical care for the taxpayer, his spouse, and dependents.

“(B) APPLICABLE PERCENTAGE.—For purposes of subparagraph (A), the applicable percentage shall be determined under the following table:

“For taxable years beginning in calendar year—	The applicable percentage is—
1997.....	40 percent
1998 through 2002.....	45 percent
2003.....	50 percent
2004.....	60 percent
2005.....	70 percent
2006 or thereafter.....	80 percent.”.

<< 26 USCA § 104 >>

(b) EXCLUSION FOR AMOUNTS RECEIVED UNDER CERTAIN SELF-INSURED PLANS.—Paragraph (3) of section 104(a) is amended by inserting “(or through an arrangement having the effect of accident or health insurance)” after “health insurance”.

<< 26 USCA §§ 104 NOTE, 162 nt >>

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1996.

Subtitle C—Long-Term Care Services and Contracts

PART I—GENERAL PROVISIONS

SEC. 321. TREATMENT OF LONG-TERM CARE INSURANCE.

<< 26 USCA § 7702B >>

(a) GENERAL RULE.—Chapter 79 (relating to definitions) is amended by inserting after section 7702A the following new section:

“SEC. 7702B. TREATMENT OF QUALIFIED LONG-TERM CARE INSURANCE.

“(a) IN GENERAL.—For purposes of this title—

“(1) a qualified long-term care insurance contract shall be treated as an accident and health insurance contract,

“(2) amounts (other than policyholder dividends, as defined in section 808, or premium refunds) received under a qualified long-term care insurance contract shall be treated as amounts received for personal injuries and sickness and shall be treated as reimbursement for expenses actually incurred for medical care (as defined in section 213(d)),

“(3) any plan of an employer providing coverage under a qualified long-term care insurance contract shall be treated as an accident and health plan with respect to such coverage,

“(4) except as provided in subsection (e)(3), amounts paid for a qualified long-term care insurance contract providing the benefits described in subsection (b)(2)(A) shall be treated as payments made for insurance for purposes of section 213(d)(1) (D), and

“(5) a qualified long-term care insurance contract shall be treated as a guaranteed renewable contract subject to the rules of section 816(e).

“(b) QUALIFIED LONG-TERM CARE INSURANCE CONTRACT.—For purposes of this title—

“(1) IN GENERAL.—The term ‘qualified long-term care insurance contract’ means any insurance contract if—

“(A) the only insurance protection provided under such contract is coverage of qualified long-term care services,

“(B) such contract does not pay or reimburse expenses incurred for services or items to the extent that such expenses are reimbursable under title XVIII of the Social Security Act or would be so reimbursable but for the application of a deductible or coinsurance amount,

“(C) such contract is guaranteed renewable,

“(D) such contract does not provide for a cash surrender value or other money that can be—

“(i) paid, assigned, or pledged as collateral for a loan, or

“(ii) borrowed,

other than as provided in subparagraph (E) or paragraph (2)(C),

“(E) all refunds of premiums, and all policyholder dividends or similar amounts, under such contract are to be applied as a reduction in future premiums or to increase future benefits, and

“(F) such contract meets the requirements of subsection (g).

“(2) SPECIAL RULES.—

“(A) PER DIEM, ETC. PAYMENTS PERMITTED.—A contract shall not fail to be described in subparagraph (A) or (B) of paragraph (1) by reason of payments being made on a per diem or other periodic basis without regard to the expenses incurred during the period to which the payments relate.

“(B) SPECIAL RULES RELATING TO MEDICARE.—

“(i) Paragraph (1)(B) shall not apply to expenses which are reimbursable under title XVIII of the Social Security Act only as a secondary payor.

“(ii) No provision of law shall be construed or applied so as to prohibit the offering of a qualified long-term care insurance contract on the basis that the contract coordinates its benefits with those provided under such title.

“(C) REFUNDS OF PREMIUMS.—Paragraph (1)(E) shall not apply to any refund on the death of the insured, or on a complete surrender or cancellation of the contract, which cannot exceed the aggregate premiums paid under the contract. Any refund on a complete surrender or cancellation of the contract shall be includible in gross income to the extent that any deduction or exclusion was allowable with respect to the premiums.

“(c) QUALIFIED LONG-TERM CARE SERVICES.—For purposes of this section—

“(1) IN GENERAL.—The term ‘qualified long-term care services’ means necessary diagnostic, preventive, therapeutic, curing, treating, mitigating, and rehabilitative services, and maintenance or personal care services, which—

“(A) are required by a chronically ill individual, and

“(B) are provided pursuant to a plan of care prescribed by a licensed health care practitioner.

“(2) CHRONICALLY ILL INDIVIDUAL.—

“(A) IN GENERAL.—The term ‘chronically ill individual’ means any individual who has been certified by a licensed health care practitioner as—

“(i) being unable to perform (without substantial assistance from another individual) at least 2 activities of daily living for a period of at least 90 days due to a loss of functional capacity,

“(ii) having a level of disability similar (as determined under regulations prescribed by the Secretary in consultation with the Secretary of Health and Human Services) to the level of disability described in clause (i), or

“(iii) requiring substantial supervision to protect such individual from threats to health and safety due to severe cognitive impairment.

Such term shall not include any individual otherwise meeting the requirements of the preceding sentence unless within the preceding 12-month period a licensed health care practitioner has certified that such individual meets such requirements.

“(B) ACTIVITIES OF DAILY LIVING.—For purposes of subparagraph (A), each of the following is an activity of daily living:

“(i) Eating.

“(ii) Toileting.

“(iii) Transferring.

“(iv) Bathing.

“(v) Dressing.

“(vi) Continence.

A contract shall not be treated as a qualified long-term care insurance contract unless the determination of whether an individual is a chronically ill individual takes into account at least 5 of such activities.

“(3) MAINTENANCE OR PERSONAL CARE SERVICES.—The term ‘maintenance or personal care services’ means any care the primary purpose of which is the provision of needed assistance with any of the disabilities as a result of which the individual is a chronically ill individual (including the protection from threats to health and safety due to severe cognitive impairment).

“(4) LICENSED HEALTH CARE PRACTITIONER.—The term ‘licensed health care practitioner’ means any physician (as defined in section 1861(r)(1) of the Social Security Act) and any registered professional nurse, licensed social worker, or other individual who meets such requirements as may be prescribed by the Secretary.

“(d) AGGREGATE PAYMENTS IN EXCESS OF LIMITS.—

“(1) IN GENERAL.—If the aggregate of—

“(A) the periodic payments received for any period under all qualified long-term care insurance contracts which are treated as made for qualified long-term care services for an insured, and

“(B) the periodic payments received for such period which are treated under section 101(g) as paid by reason of the death of such insured,

exceeds the per diem limitation for such period, such excess shall be includible in gross income without regard to section 72. A payment shall not be taken into account under subparagraph (B) if the insured is a terminally ill individual (as defined in section 101(g)) at the time the payment is received.

“(2) PER DIEM LIMITATION.—For purposes of paragraph (1), the per diem limitation for any period is an amount equal to the excess (if any) of—

“(A) the greater of—

“(i) the dollar amount in effect for such period under paragraph (4), or

“(ii) the costs incurred for qualified long-term care services provided for the insured for such period, over

“(B) the aggregate payments received as reimbursements (through insurance or otherwise) for qualified long-term care services provided for the insured during such period.

“(3) AGGREGATION RULES.—For purposes of this subsection—

“(A) all persons receiving periodic payments described in paragraph (1) with respect to the same insured shall be treated as 1 person, and

“(B) the per diem limitation determined under paragraph (2) shall be allocated first to the insured and any remaining limitation shall be allocated among the other such persons in such manner as the Secretary shall prescribe.

“(4) DOLLAR AMOUNT.—The dollar amount in effect under this subsection shall be \$175 per day (or the equivalent amount in the case of payments on another periodic basis).

“(5) INFLATION ADJUSTMENT.—In the case of a calendar year after 1997, the dollar amount contained in paragraph (4) shall be increased at the same time and in the same manner as amounts are increased pursuant to section 213(d)(10).

“(6) PERIODIC PAYMENTS.—For purposes of this subsection, the term ‘periodic payment’ means any payment (whether on a periodic basis or otherwise) made without regard to the extent of the costs incurred by the payee for qualified long-term care services.

“(e) TREATMENT OF COVERAGE PROVIDED AS PART OF A LIFE INSURANCE CONTRACT.—Except as otherwise provided in regulations prescribed by the Secretary, in the case of any long-term care insurance coverage (whether or not qualified) provided by a rider on or as part of a life insurance contract—

“(1) IN GENERAL.—This section shall apply as if the portion of the contract providing such coverage is a separate contract.

“(2) APPLICATION OF 7702.—Section 7702(c)(2) (relating to the guideline premium limitation) shall be applied by increasing the guideline premium limitation with respect to a life insurance contract, as of any date—

“(A) by the sum of any charges (but not premium payments) against the life insurance contract's cash surrender value (within the meaning of section 7702(f)(2)(A)) for such coverage made to that date under the contract, less

“(B) any such charges the imposition of which reduces the premiums paid for the contract (within the meaning of section 7702(f)(1)).

“(3) APPLICATION OF SECTION 213.—No deduction shall be allowed under section 213(a) for charges against the life insurance contract's cash surrender value described in paragraph (2), unless such charges are includible in income as a result of the application of section 72(e)(10) and the rider is a qualified long-term care insurance contract under subsection (b).

“(4) PORTION DEFINED.—For purposes of this subsection, the term ‘portion’ means only the terms and benefits under a life insurance contract that are in addition to the terms and benefits under the contract without regard to long-term care insurance coverage.

“(f) TREATMENT OF CERTAIN STATE-MAINTAINED PLANS.—

“(1) IN GENERAL.—If—

“(A) an individual receives coverage for qualified long-term care services under a State long-term care plan, and

“(B) the terms of such plan would satisfy the requirements of subsection (b) were such plan an insurance contract,

such plan shall be treated as a qualified long-term care insurance contract for purposes of this title.

“(2) STATE LONG-TERM CARE PLAN.—For purposes of paragraph (1), the term ‘State long-term care plan’ means any plan—

“(A) which is established and maintained by a State or an instrumentality of a State,

“(B) which provides coverage only for qualified long-term care services, and

“(C) under which such coverage is provided only to—

“(i) employees and former employees of a State (or any political subdivision or instrumentality of a State),

“(ii) the spouses of such employees, and

“(iii) individuals bearing a relationship to such employees or spouses which is described in any of paragraphs (1) through (8) of section 152(a).”.

<< 26 USCA § 807 >>

(b) RESERVE METHOD.—Clause (iii) of section 807(d)(3)(A) is amended by inserting “(other than a qualified long-term care insurance contract, as defined in section 7702B(b))” after “insurance contract”.

(c) LONG-TERM CARE INSURANCE NOT PERMITTED UNDER CAFETERIA PLANS OR FLEXIBLE SPENDING ARRANGEMENTS.—

<< 26 USCA § 125 >>

(1) CAFETERIA PLANS.—Section 125(f) is amended by adding at the end the following new sentence: “Such term shall not include any product which is advertised, marketed, or offered as long-term care insurance.”.

<< 26 USCA § 106 >>

(2) FLEXIBLE SPENDING ARRANGEMENTS.—Section 106 (relating to contributions by employer to accident and health plans), as amended by section 301(c), is amended by adding at the end the following new subsection:

“(c) INCLUSION OF LONG-TERM CARE BENEFITS PROVIDED THROUGH FLEXIBLE SPENDING ARRANGEMENTS.—

“(1) IN GENERAL.—Effective on and after January 1, 1997, gross income of an employee shall include employer-provided coverage for qualified long-term care services (as defined in section 7702B(c)) to the extent that such coverage is provided through a flexible spending or similar arrangement.

“(2) FLEXIBLE SPENDING ARRANGEMENT.—For purposes of this subsection, a flexible spending arrangement is a benefit program which provides employees with coverage under which—

“(A) specified incurred expenses may be reimbursed (subject to reimbursement maximums and other reasonable conditions), and

“(B) the maximum amount of reimbursement which is reasonably available to a participant for such coverage is less than 500 percent of the value of such coverage.

In the case of an insured plan, the maximum amount reasonably available shall be determined on the basis of the underlying coverage.”

(d) CONTINUATION COVERAGE RULES NOT TO APPLY.—

<< 26 USCA § 4980B >>

(1) Paragraph (2) of section 4980B(g) is amended by adding at the end the following new sentence: “Such term shall not include any plan substantially all of the coverage under which is for qualified long-term care services (as defined in section 7702B(c)).”

<< 29 USCA § 1167 >>

(2) Paragraph (1) of section 607 of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new sentence: “Such term shall not include any plan substantially all of the coverage under which is for qualified long-term care services (as defined in section 7702B(c) of such Code).”

<< 42 USCA § 300bb-8 >>

(3) Paragraph (1) of section 2208 of the Public Health Service Act is amended by adding at the end the following new sentence: “Such term shall not include any plan substantially all of the coverage under which is for qualified long-term care services (as defined in section 7702B(c) of such Code).”

<< 26 USCA Ch. 79 >>

(e) CLERICAL AMENDMENT.—The table of sections for chapter 79 is amended by inserting after the item relating to section 7702A the following new item:

“Sec. 7702B. Treatment of qualified long-term care insurance.”.

<< 26 USCA §§ 106 nt, 125 nt, 807 nt, 4980B nt >>

<< 26 USCA § 7702B NOTE >>

<< 29 USCA § 1167 nt >>

<< 42 USCA § 300bb-8 nt >>

(f) EFFECTIVE DATES.—

(1) GENERAL EFFECTIVE DATE.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the amendments made by this section shall apply to contracts issued after December 31, 1996.

(B) RESERVE METHOD.—The amendment made by subsection (b) shall apply to contracts issued after December 31, 1997.

(2) CONTINUATION OF EXISTING POLICIES.—In the case of any contract issued before January 1, 1997, which met the long-term care insurance requirements of the State in which the contract was situated at the time the contract was issued—

(A) such contract shall be treated for purposes of the Internal Revenue Code of 1986 as a qualified long-term care insurance contract (as defined in section 7702B(b) of such Code), and

(B) services provided under, or reimbursed by, such contract shall be treated for such purposes as qualified long-term care services (as defined in section 7702B(c) of such Code).

In the case of an individual who is covered on December 31, 1996, under a State long-term care plan (as defined in section 7702B(f)(2) of such Code), the terms of such plan on such date shall be treated for purposes of the preceding sentence as a contract issued on such date which met the long-term care insurance requirements of such State.

(3) EXCHANGES OF EXISTING POLICIES.—If, after the date of enactment of this Act and before January 1, 1998, a contract providing for long-term care insurance coverage is exchanged solely for a qualified long-term care insurance contract (as defined in section 7702B(b) of such Code), no gain or loss shall be recognized on the exchange. If, in addition to a qualified long-term care insurance contract, money or other property is received in the exchange, then any gain shall be recognized to the extent of the sum of the money and the fair market value of the other property received. For purposes of this paragraph, the cancellation of a contract providing for long-term care insurance coverage and reinvestment of the cancellation proceeds in a qualified long-term care insurance contract within 60 days thereafter shall be treated as an exchange.

(4) ISSUANCE OF CERTAIN RIDERS PERMITTED.—For purposes of applying sections 101(f), 7702, and 7702A of the Internal Revenue Code of 1986 to any contract—

(A) the issuance of a rider which is treated as a qualified long-term care insurance contract under section 7702B, and

(B) the addition of any provision required to conform any other long-term care rider to be so treated,

shall not be treated as a modification or material change of such contract.

(5) APPLICATION OF PER DIEM LIMITATION TO EXISTING CONTRACTS.—The amount of per diem payments made under a contract issued on or before July 31, 1996, with respect to an insured which are excludable from gross income by reason of section 7702B of the Internal Revenue Code of 1986 (as added by this section) shall not be reduced under subsection (d)(2)(B) thereof by reason of reimbursements received under a contract issued on or before such date. The preceding sentence shall cease to apply as of the date (after July 31, 1996) such contract is exchanged or there is any contract modification which results in an increase in the amount of such per diem payments or the amount of such reimbursements.

<< 26 USCA § 7702B NOTE >>

(g) LONG-TERM CARE STUDY REQUEST.—The Chairman of the Committee on Ways and Means of the House of Representatives and the Chairman of the Committee on Finance of the Senate shall jointly request the National Association of Insurance Commissioners, in consultation with representatives of the insurance industry and consumer organizations, to formulate, develop, and conduct a study to determine the marketing and other effects of per diem limits on certain types of long-term care policies. If the National Association of Insurance Commissioners agrees to the study request, the National Association of Insurance Commissioners shall report the results of its study to such committees not later than 2 years after accepting the request.

SEC. 322. QUALIFIED LONG-TERM CARE SERVICES TREATED AS MEDICAL CARE.

<< 26 USCA § 213 >>

(a) GENERAL RULE.—Paragraph (1) of section 213(d) (defining medical care) is amended by striking “or” at the end of subparagraph (B), by redesignating subparagraph (C) as subparagraph (D), and by inserting after subparagraph (B) the following new subparagraph:

“(C) for qualified long-term care services (as defined in section 7702B(c)), or”.

(b) TECHNICAL AMENDMENTS.—

(1) Subparagraph (D) of section 213(d)(1) (as redesignated by subsection (a)) is amended by inserting before the period “or for any qualified long-term care insurance contract (as defined in section 7702B(b))”.

(2)(A) Paragraph (1) of section 213(d) is amended by adding at the end the following new flush sentence:

“In the case of a qualified long-term care insurance contract (as defined in section 7702B(b)), only eligible long-term care premiums (as defined in paragraph (10)) shall be taken into account under subparagraph (D).”

<< 26 USCA § 162 >>

(B) Paragraph (2) of section 162(l) is amended by adding at the end the following new subparagraph:

“(C) LONG-TERM CARE PREMIUMS.—In the case of a qualified long-term care insurance contract (as defined in section 7702B(b)), only eligible long-term care premiums (as defined in section 213(d)(10)) shall be taken into account under paragraph (1).”

<< 26 USCA § 213 >>

(C) Subsection (d) of section 213 is amended by adding at the end the following new paragraphs:

“(10) ELIGIBLE LONG-TERM CARE PREMIUMS.—

“(A) IN GENERAL.—For purposes of this section, the term ‘eligible long-term care premiums’ means the amount paid during a taxable year for any qualified long-term care insurance contract (as defined in section 7702B(b)) covering an individual, to the extent such amount does not exceed the limitation determined under the following table:

“In the case of an individual

with an attained age before the	The limitation
close of the taxable year of:	is:
40 or less.....	\$ 200
More than 40 but not more than 50.....	375
More than 50 but not more than 60.....	750
More than 60 but not more than 70.....	2,000
More than 70.....	2,500.

“(B) INDEXING.—

“(i) IN GENERAL.—In the case of any taxable year beginning in a calendar year after 1997, each dollar amount contained in subparagraph (A) shall be increased by the medical care cost adjustment of such amount for such calendar year. If any increase determined under the preceding sentence is not a multiple of \$10, such increase shall be rounded to the nearest multiple of \$10.

“(ii) MEDICAL CARE COST ADJUSTMENT.—For purposes of clause (i), the medical care cost adjustment for any calendar year is the percentage (if any) by which—

“(I) the medical care component of the Consumer Price Index (as defined in section 1(f)(5)) for August of the preceding calendar year, exceeds

“(II) such component for August of 1996.

The Secretary shall, in consultation with the Secretary of Health and Human Services, prescribe an adjustment which the Secretary determines is more appropriate for purposes of this paragraph than the adjustment described in the preceding sentence, and the adjustment so prescribed shall apply in lieu of the adjustment described in the preceding sentence.

“(11) CERTAIN PAYMENTS TO RELATIVES TREATED AS NOT PAID FOR MEDICAL CARE.—An amount paid for a qualified long-term care service (as defined in section 7702B(c)) provided to an individual shall be treated as not paid for medical care if such service is provided—

“(A) by the spouse of the individual or by a relative (directly or through a partnership, corporation, or other entity) unless the service is provided by a licensed professional with respect to such service, or

“(B) by a corporation or partnership which is related (within the meaning of section 267(b) or 707(b)) to the individual.

For purposes of this paragraph, the term ‘relative’ means an individual bearing a relationship to the individual which is described in any of paragraphs (1) through (8) of section 152(a). This paragraph shall not apply for purposes of section 105(b) with respect to reimbursements through insurance.”.

(3) Paragraph (6) of section 213(d) is amended—

(A) by striking “subparagraphs (A) and (B)” and inserting “subparagraphs (A), (B), and (C)”, and

(B) by striking “paragraph (1)(C)” in subparagraph (A) and inserting “paragraph (1)(D)”.

(4) Paragraph (7) of section 213(d) is amended by striking “subparagraphs (A) and (B)” and inserting “subparagraphs (A), (B), and (C)”.

<< 26 USCA §§ 162 NOTE, 213 nt >>

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1996.

SEC. 323. REPORTING REQUIREMENTS.

<< 26 USCA § 6050Q >>

(a) IN GENERAL.—Subpart B of part III of subchapter A of chapter 61 is amended by adding at the end the following new section:

“SEC. 6050Q. CERTAIN LONG-TERM CARE BENEFITS.

“(a) REQUIREMENT OF REPORTING.—Any person who pays long-term care benefits shall make a return, according to the forms or regulations prescribed by the Secretary, setting forth—

“(1) the aggregate amount of such benefits paid by such person to any individual during any calendar year,

“(2) whether or not such benefits are paid in whole or in part on a per diem or other periodic basis without regard to the expenses incurred during the period to which the payments relate,

“(3) the name, address, and TIN of such individual, and

“(4) the name, address, and TIN of the chronically ill or terminally ill individual on account of whose condition such benefits are paid.

“(b) STATEMENTS TO BE FURNISHED TO PERSONS WITH RESPECT TO WHOM INFORMATION IS REQUIRED.—Every person required to make a return under subsection (a) shall furnish to each individual whose name is required to be set forth in such return a written statement showing—

“(1) the name of the person making the payments, and

“(2) the aggregate amount of long-term care benefits paid to the individual which are required to be shown on such return.

The written statement required under the preceding sentence shall be furnished to the individual on or before January 31 of the year following the calendar year for which the return under subsection (a) was required to be made.

“(c) LONG-TERM CARE BENEFITS.—For purposes of this section, the term ‘long-term care benefit’ means—

“(1) any payment under a product which is advertised, marketed, or offered as long-term care insurance, and

“(2) any payment which is excludable from gross income by reason of section 101(g).”.

<< 26 USCA § 6724 >>

(b) PENALTIES.—

(1) Subparagraph (B) of section 6724(d)(1) is amended by redesignating clauses (ix) through (xiv) as clauses (x) through (xv), respectively, and by inserting after clause (viii) the following new clause:

“(ix) section 6050Q (relating to certain long-term care benefits),”.

(2) Paragraph (2) of section 6724(d) is amended by redesignating subparagraphs (Q) through (T) as subparagraphs (R) through (U), respectively, and by inserting after subparagraph (P) the following new subparagraph:

“(Q) section 6050Q(b) (relating to certain long-term care benefits),”.

<< 26 USCA Ch. 61 >>

(c) CLERICAL AMENDMENT.—The table of sections for subpart B of part III of subchapter A of chapter 61 is amended by adding at the end the following new item:

“Sec. 6050Q. Certain long-term care benefits.”.

<< 26 USCA § 6050Q NOTE >>

<< 26 USCA § 6724 nt >>

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to benefits paid after December 31, 1996.

PART II—CONSUMER PROTECTION PROVISIONS

<< 26 USCA § 7702B >>

SEC. 325. POLICY REQUIREMENTS.

Section 7702B (as added by section 321) is amended by adding at the end the following new subsection:

“(g) CONSUMER PROTECTION PROVISIONS.—

“(1) IN GENERAL.—The requirements of this subsection are met with respect to any contract if the contract meets—

“(A) the requirements of the model regulation and model Act described in paragraph (2),

“(B) the disclosure requirement of paragraph (3), and

“(C) the requirements relating to nonforfeitability under paragraph (4).

“(2) REQUIREMENTS OF MODEL REGULATION AND ACT.—

“(A) IN GENERAL.—The requirements of this paragraph are met with respect to any contract if such contract meets—

“(i) MODEL REGULATION.—The following requirements of the model regulation:

“(I) Section 7A (relating to guaranteed renewal or noncancellability), and the requirements of section 6B of the model Act relating to such section 7A.

“(II) Section 7B (relating to prohibitions on limitations and exclusions).

“(III) Section 7C (relating to extension of benefits).

“(IV) Section 7D (relating to continuation or conversion of coverage).

“(V) Section 7E (relating to discontinuance and replacement of policies).

“(VI) Section 8 (relating to unintentional lapse).

“(VII) Section 9 (relating to disclosure), other than section 9F thereof.

“(VIII) Section 10 (relating to prohibitions against post-claims underwriting).

“(IX) Section 11 (relating to minimum standards).

“(X) Section 12 (relating to requirement to offer inflation protection), except that any requirement for a signature on a rejection of inflation protection shall permit the signature to be on an application or on a separate form.

“(XI) Section 23 (relating to prohibition against preexisting conditions and probationary periods in replacement policies or certificates).

“(ii) MODEL ACT.—The following requirements of the model Act:

“(I) Section 6C (relating to preexisting conditions).

“(II) Section 6D (relating to prior hospitalization).

“(B) DEFINITIONS.—For purposes of this paragraph—

“(i) MODEL PROVISIONS.—The terms ‘model regulation’ and ‘model Act’ mean the long-term care insurance model regulation, and the long-term care insurance model Act, respectively, promulgated by the National Association of Insurance Commissioners (as adopted as of January 1993).

“(ii) COORDINATION.—Any provision of the model regulation or model Act listed under clause (i) or (ii) of subparagraph (A) shall be treated as including any other provision of such regulation or Act necessary to implement the provision.

“(iii) DETERMINATION.—For purposes of this section and section 4980C, the determination of whether any requirement of a model regulation or the model Act has been met shall be made by the Secretary.

“(3) DISCLOSURE REQUIREMENT.—The requirement of this paragraph is met with respect to any contract if such contract meets the requirements of section 4980C(d).

“(4) NONFORFEITURE REQUIREMENTS.—

“(A) IN GENERAL.—The requirements of this paragraph are met with respect to any level premium contract, if the issuer of such contract offers to the policyholder, including any group policyholder, a nonforfeiture provision meeting the requirements of subparagraph (B).

“(B) REQUIREMENTS OF PROVISION.—The nonforfeiture provision required under subparagraph (A) shall meet the following requirements:

“(i) The nonforfeiture provision shall be appropriately captioned.

“(ii) The nonforfeiture provision shall provide for a benefit available in the event of a default in the payment of any premiums and the amount of the benefit may be adjusted subsequent to being initially granted only as necessary to reflect changes in claims, persistency, and interest as reflected in changes in rates for premium paying contracts approved by the Secretary for the same contract form.

“(iii) The nonforfeiture provision shall provide at least one of the following:

“(I) Reduced paid-up insurance.

“(II) Extended term insurance.

“(III) Shortened benefit period.

“(IV) Other similar offerings approved by the Secretary.

“(5) CROSS REFERENCE.—

“For coordination of the requirements of this subsection with State requirements, see section 4980C(f).”.

SEC. 326. REQUIREMENTS FOR ISSUERS OF QUALIFIED LONG-TERM CARE INSURANCE CONTRACTS.

<< 26 USCA § 4980C >>

(a) IN GENERAL.—Chapter 43 is amended by adding at the end the following new section:

“SEC. 4980C. REQUIREMENTS FOR ISSUERS OF QUALIFIED LONG-TERM CARE INSURANCE CONTRACTS.

“(a) GENERAL RULE.—There is hereby imposed on any person failing to meet the requirements of subsection (c) or (d) a tax in the amount determined under subsection (b).

“(b) AMOUNT.—

“(1) IN GENERAL.—The amount of the tax imposed by subsection (a) shall be \$100 per insured for each day any requirement of subsection (c) or (d) is not met with respect to each qualified long-term care insurance contract.

“(2) WAIVER.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the tax imposed by subsection (a) to the extent that payment of the tax would be excessive relative to the failure involved.

“(c) RESPONSIBILITIES.—The requirements of this subsection are as follows:

“(1) REQUIREMENTS OF MODEL PROVISIONS.—

“(A) MODEL REGULATION.—The following requirements of the model regulation must be met:

“(i) Section 13 (relating to application forms and replacement coverage).

“(ii) Section 14 (relating to reporting requirements), except that the issuer shall also report at least annually the number of claims denied during the reporting period for each class of business (expressed as a percentage of claims denied), other than claims denied for failure to meet the waiting period or because of any applicable preexisting condition.

“(iii) Section 20 (relating to filing requirements for marketing).

“(iv) Section 21 (relating to standards for marketing), including inaccurate completion of medical histories, other than sections 21C(1) and 21C(6) thereof, except that—

“(I) in addition to such requirements, no person shall, in selling or offering to sell a qualified long-term care insurance contract, misrepresent a material fact; and

“(II) no such requirements shall include a requirement to inquire or identify whether a prospective applicant or enrollee for long-term care insurance has accident and sickness insurance.

“(v) Section 22 (relating to appropriateness of recommended purchase).

“(vi) Section 24 (relating to standard format outline of coverage).

“(vii) Section 25 (relating to requirement to deliver shopper's guide).

“(B) MODEL ACT.—The following requirements of the model Act must be met:

“(i) Section 6F (relating to right to return), except that such section shall also apply to denials of applications and any refund shall be made within 30 days of the return or denial.

“(ii) Section 6G (relating to outline of coverage).

“(iii) Section 6H (relating to requirements for certificates under group plans).

“(iv) Section 6I (relating to policy summary).

“(v) Section 6J (relating to monthly reports on accelerated death benefits).

“(vi) Section 7 (relating to incontestability period).

“(C) DEFINITIONS.—For purposes of this paragraph, the terms ‘model regulation’ and ‘model Act’ have the meanings given such terms by section 7702B(g)(2)(B).

“(2) DELIVERY OF POLICY.—If an application for a qualified long-term care insurance contract (or for a certificate under such a contract for a group) is approved, the issuer shall deliver to the applicant (or policyholder or certificateholder) the contract (or certificate) of insurance not later than 30 days after the date of the approval.

“(3) INFORMATION ON DENIALS OF CLAIMS.—If a claim under a qualified, long-term care insurance contract is denied, the issuer shall, within 60 days of the date of a written request by the policyholder or certificateholder (or representative)—

“(A) provide a written explanation of the reasons for the denial, and

“(B) make available all information directly relating to such denial.

“(d) DISCLOSURE.—The requirements of this subsection are met if the issuer of a long-term care insurance policy discloses in such policy and in the outline of coverage required under subsection (c)(1)(B)(ii) that the policy is intended to be a qualified long-term care insurance contract under section 7702B(b).

“(e) QUALIFIED LONG-TERM CARE INSURANCE CONTRACT DEFINED.—For purposes of this section, the term ‘qualified long-term care insurance contract’ has the meaning given such term by section 7702B.

“(f) COORDINATION WITH STATE REQUIREMENTS.—If a State imposes any requirement which is more stringent than the analogous requirement imposed by this section or section 7702B(g), the requirement imposed by this section or section 7702B(g) shall be treated as met if the more stringent State requirement is met.”.

<< 26 USCA Ch. 43 >>

(b) CONFORMING AMENDMENT.—The table of sections for chapter 43 is amended by adding at the end the following new item:

“Sec. 4980C. Requirements for issuers of qualified long-term care insurance contracts.”.

<< 26 USCA § 4980C NOTE >>

SEC. 327. EFFECTIVE DATES.

(a) IN GENERAL.—The provisions of, and amendments made by, this part shall apply to contracts issued after December 31, 1996. The provisions of section 321(f) (relating to transition rule) shall apply to such contracts.

(b) ISSUERS.—The amendments made by section 326 shall apply to actions taken after December 31, 1996.

Subtitle D—Treatment of Accelerated Death Benefits

SEC. 331. TREATMENT OF ACCELERATED DEATH BENEFITS BY RECIPIENT.

<< 26 USCA § 101 >>

(a) IN GENERAL.—Section 101 (relating to certain death benefits) is amended by adding at the end the following new subsection:

“(g) TREATMENT OF CERTAIN ACCELERATED DEATH BENEFITS.—

“(1) IN GENERAL.—For purposes of this section, the following amounts shall be treated as an amount paid by reason of the death of an insured:

“(A) Any amount received under a life insurance contract on the life of an insured who is a terminally ill individual.

“(B) Any amount received under a life insurance contract on the life of an insured who is a chronically ill individual.

“(2) TREATMENT OF VIATICAL SETTLEMENTS.—

“(A) IN GENERAL.—If any portion of the death benefit under a life insurance contract on the life of an insured described in paragraph (1) is sold or assigned to a viatical settlement provider, the amount paid for the sale or assignment of such portion shall be treated as an amount paid under the life insurance contract by reason of the death of such insured.

“(B) VIATICAL SETTLEMENT PROVIDER.—

“(i) IN GENERAL.—The term ‘viatical settlement provider’ means any person regularly engaged in the trade or business of purchasing, or taking assignments of, life insurance contracts on the lives of insureds described in paragraph (1) if—

“(I) such person is licensed for such purposes (with respect to insureds described in the same subparagraph of paragraph (1) as the insured) in the State in which the insured resides, or

“(II) in the case of an insured who resides in a State not requiring the licensing of such persons for such purposes with respect to such insured, such person meets the requirements of clause (ii) or (iii), whichever applies to such insured.

“(ii) TERMINALLY ILL INSURED.—A person meets the requirements of this clause with respect to an insured who is a terminally ill individual if such person—

“(I) meets the requirements of sections 8 and 9 of the Viatical Settlements Model Act of the National Association of Insurance Commissioners, and

“(II) meets the requirements of the Model Regulations of the National Association of Insurance Commissioners (relating to standards for evaluation of reasonable payments) in determining amounts paid by such person in connection with such purchases or assignments.

“(iii) CHRONICALLY ILL INSURED.—A person meets the requirements of this clause with respect to an insured who is a chronically ill individual if such person—

“(I) meets requirements similar to the requirements referred to in clause (ii)(I), and

“(II) meets the standards (if any) of the National Association of Insurance Commissioners for evaluating the reasonableness of amounts paid by such person in connection with such purchases or assignments with respect to chronically ill individuals.

“(3) SPECIAL RULES FOR CHRONICALLY ILL INSURED.—In the case of an insured who is a chronically ill individual

—
“(A) IN GENERAL.—Paragraphs (1) and (2) shall not apply to any payment received for any period unless—

- “(i) such payment is for costs incurred by the payee (not compensated for by insurance or otherwise) for qualified long-term care services provided for the insured for such period, and
- “(ii) the terms of the contract giving rise to such payment satisfy—
 - “(I) the requirements of section 7702B(b)(1)(B), and
 - “(II) the requirements (if any) applicable under subparagraph (B).

For purposes of the preceding sentence, the rule of section 7702B(b)(2)(B) shall apply.

“(B) OTHER REQUIREMENTS.—The requirements applicable under this subparagraph are—

“(i) those requirements of section 7702B(g) and section 4980C which the Secretary specifies as applying to such a purchase, assignment, or other arrangement,

“(ii) standards adopted by the National Association of Insurance Commissioners which specifically apply to chronically ill individuals (and, if such standards are adopted, the analogous requirements specified under clause (i) shall cease to apply), and

“(iii) standards adopted by the State in which the policyholder resides (and if such standards are adopted, the analogous requirements specified under clause (i) and (subject to section 4980C(f)) standards under clause (ii), shall cease to apply).

“(C) PER DIEM PAYMENTS.—A payment shall not fail to be described in subparagraph (A) by reason of being made on a per diem or other periodic basis without regard to the expenses incurred during the period to which the payment relates.

“(D) LIMITATION ON EXCLUSION FOR PERIODIC PAYMENTS.—

“For limitation on amount of periodic payments which are treated as described in paragraph (1), see section 7702B(d).”.

“(4) DEFINITIONS.—For purposes of this subsection—

“(A) TERMINALLY ILL INDIVIDUAL.—The term ‘terminally ill individual’ means an individual who has been certified by a physician as having an illness or physical condition which can reasonably be expected to result in death in 24 months or less after the date of the certification.

“(B) CHRONICALLY ILL INDIVIDUAL.—The term ‘chronically ill individual’ has the meaning given such term by section 7702B(c)(2); except that such term shall not include a terminally ill individual.

“(C) QUALIFIED LONG-TERM CARE SERVICES.—The term ‘qualified long-term care services’ has the meaning given such term by section 7702B(c).

“(D) PHYSICIAN.—The term ‘physician’ has the meaning given to such term by section 1861(r)(1) of the Social Security Act (42 U.S.C. 1395x(r)(1)).

“(5) EXCEPTION FOR BUSINESS-RELATED POLICIES.—This subsection shall not apply in the case of any amount paid to any taxpayer other than the insured if such taxpayer has an insurable interest with respect to the life of the insured by reason of the insured being a director, officer, or employee of the taxpayer or by reason of the insured being financially interested in any trade or business carried on by the taxpayer.”.

<< 26 USCA § 101 NOTE >>

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to amounts received after December 31, 1996.

SEC. 332. TAX TREATMENT OF COMPANIES ISSUING QUALIFIED ACCELERATED DEATH BENEFIT RIDERS.

<< 26 USCA § 818 >>

(a) QUALIFIED ACCELERATED DEATH BENEFIT RIDERS TREATED AS LIFE INSURANCE.—Section 818 (relating to other definitions and special rules) is amended by adding at the end the following new subsection:

“(g) QUALIFIED ACCELERATED DEATH BENEFIT RIDERS TREATED AS LIFE INSURANCE.—For purposes of this part—

“(1) IN GENERAL.—Any reference to a life insurance contract shall be treated as including a reference to a qualified accelerated death benefit rider on such contract.

“(2) QUALIFIED ACCELERATED DEATH BENEFIT RIDERS.—For purposes of this subsection, the term ‘qualified accelerated death benefit rider’ means any rider on a life insurance contract if the only payments under the rider are payments meeting the requirements of section 101(g).

“(3) EXCEPTION FOR LONG-TERM CARE RIDERS.—Paragraph (1) shall not apply to any rider which is treated as a long-term care insurance contract under section 7702B.”.

(b) EFFECTIVE DATE.—

<< 26 USCA § 818 NOTE >>

(1) IN GENERAL.—The amendment made by this section shall take effect on January 1, 1997.

(2) ISSUANCE OF RIDER NOT TREATED AS MATERIAL CHANGE.—For purposes of applying sections 101(f), 7702, and 7702A of the Internal Revenue Code of 1986 to any contract—

(A) the issuance of a qualified accelerated death benefit rider (as defined in section 818(g) of such Code (as added by this Act)), and

(B) the addition of any provision required to conform an accelerated death benefit rider to the requirements of such section 818(g),

shall not be treated as a modification or material change of such contract.

Subtitle E—State Insurance Pools

SEC. 341. EXEMPTION FROM INCOME TAX FOR STATE-SPONSORED ORGANIZATIONS PROVIDING HEALTH COVERAGE FOR HIGH-RISK INDIVIDUALS.

<< 26 USCA § 501 >>

(a) IN GENERAL.—Subsection (c) of section 501 (relating to list of exempt organizations) is amended by adding at the end the following new paragraph:

“(26) Any membership organization if—

“(A) such organization is established by a State exclusively to provide coverage for medical care (as defined in section 213(d)) on a not-for-profit basis to individuals described in subparagraph (B) through—

“(i) insurance issued by the organization, or

“(ii) a health maintenance organization under an arrangement with the organization,

“(B) the only individuals receiving such coverage through the organization are individuals—

“(i) who are residents of such State, and

“(ii) who, by reason of the existence or history of a medical condition—

“(I) are unable to acquire medical care coverage for such condition through insurance or from a health maintenance organization, or

“(II) are able to acquire such coverage only at a rate which is substantially in excess of the rate for such coverage through the membership organization,

“(C) the composition of the membership in such organization is specified by such State, and

“(D) no part of the net earnings of the organization inures to the benefit of any private shareholder or individual.”.

<< 26 USCA § 501 NOTE >>

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 1996.

SEC. 342. EXEMPTION FROM INCOME TAX FOR STATE-SPONSORED WORKMEN'S COMPENSATION REINSURANCE ORGANIZATIONS.

<< 26 USCA § 501 >>

(a) IN GENERAL.—Subsection (c) of section 501 (relating to list of exempt organizations), as amended by section 341, is amended by adding at the end the following new paragraph:

“(27) Any membership organization if—

- “(A) such organization is established before June 1, 1996, by a State exclusively to reimburse its members for losses arising under workmen's compensation acts,
- “(B) such State requires that the membership of such organization consist of—
- “(i) all persons who issue insurance covering workmen's compensation losses in such State, and
- “(ii) all persons and governmental entities who self-insure against such losses, and
- “(C) such organization operates as a non-profit organization by—
- “(i) returning surplus income to its members or workmen's compensation policyholders on a periodic basis, and
- “(ii) reducing initial premiums in anticipation of investment income.”.

<< 26 USCA § 501 NOTE >>

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years ending after the date of the enactment of this Act.

Subtitle F—Organizations Subject to Section 833

SEC. 351. ORGANIZATIONS SUBJECT TO SECTION 833.

<< 26 USCA § 833 >>

(a) IN GENERAL.—Section 833(c) (relating to organization to which section applies) is amended by adding at the end the following new paragraph:

“(4) TREATMENT AS EXISTING BLUE CROSS OR BLUE SHIELD ORGANIZATION.—

“(A) IN GENERAL.—Paragraph (2) shall be applied to an organization described in subparagraph (B) as if it were a Blue Cross or Blue Shield organization.

“(B) APPLICABLE ORGANIZATION.—An organization is described in this subparagraph if it—

“(i) is organized under, and governed by, State laws which are specifically and exclusively applicable to not-for-profit health insurance or health service type organizations, and

“(ii) is not a Blue Cross or Blue Shield organization or health maintenance organization.”.

<< 26 USCA § 833 NOTE >>

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years ending after December 31, 1996.

Subtitle G—IRA Distributions to the Unemployed

SEC. 361. DISTRIBUTIONS FROM CERTAIN PLANS MAY BE USED WITHOUT ADDITIONAL TAX TO PAY FINANCIALLY DEVASTATING MEDICAL EXPENSES.

<< 26 USCA § 72 >>

(a) IN GENERAL.—Section 72(t)(3)(A) is amended by striking “(B).”.

(b) DISTRIBUTIONS FOR PAYMENT OF HEALTH INSURANCE PREMIUMS OF CERTAIN UNEMPLOYED INDIVIDUALS.—Paragraph (2) of section 72(t) is amended by adding at the end the following new subparagraph:

“(D) DISTRIBUTIONS TO UNEMPLOYED INDIVIDUALS FOR HEALTH INSURANCE PREMIUMS.—

“(i) IN GENERAL.—Distributions from an individual retirement plan to an individual after separation from employment—

“(I) if such individual has received unemployment compensation for 12 consecutive weeks under any Federal or State unemployment compensation law by reason of such separation,

“(II) if such distributions are made during any taxable year during which such unemployment compensation is paid or the succeeding taxable year, and

“(III) to the extent such distributions do not exceed the amount paid during the taxable year for insurance described in section 213(d)(1)(D) with respect to the individual and the individual's spouse and dependents (as defined in section 152).

“(ii) DISTRIBUTIONS AFTER REEMPLOYMENT.—Clause (i) shall not apply to any distribution made after the individual has been employed for at least 60 days after the separation from employment to which clause (i) applies.

“(iii) SELF-EMPLOYED INDIVIDUALS.—To the extent provided in regulations, a self-employed individual shall be treated as meeting the requirements of clause (i)(I) if, under Federal or State law, the individual would have received unemployment compensation but for the fact the individual was self-employed.”.

(c) CONFORMING AMENDMENT.—Subparagraph (B) of section 72(t)(2) is amended by striking “or (C)” and inserting “, (C), or (D)”.

<< 26 USCA § 72 NOTE >>

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to distributions after December 31, 1996.

Subtitle H—Organ and Tissue Donation Information Included With Income Tax Refund Payments

<< 26 USCA § 6402 NOTE >>

SEC. 371. ORGAN AND TISSUE DONATION INFORMATION INCLUDED WITH INCOME TAX REFUND PAYMENTS.

(a) IN GENERAL.—The Secretary of the Treasury shall, to the extent practicable, include with the mailing of any payment of a refund of individual income tax made during the period beginning on February 1, 1997, and ending on June 30, 1997, a copy of the document described in subsection (b).

(b) TEXT OF DOCUMENT.—The Secretary of the Treasury shall, after consultation with the Secretary of Health and Human Services and organizations promoting organ and tissue (including eye) donation, prepare a document suitable for inclusion with individual income tax refund payments which—

- (1) encourages organ and tissue donation;
- (2) includes a detachable organ and tissue donor card; and
- (3) urges recipients to—
 - (A) sign the organ and tissue donor card;
 - (B) discuss organ and tissue donation with family members and tell family members about the recipient's desire to be an organ and tissue donor if the occasion arises; and
 - (C) encourage family members to request or authorize organ and tissue donation if the occasion arises.

TITLE IV—APPLICATION AND ENFORCEMENT OF GROUP HEALTH PLAN REQUIREMENTS

Subtitle A—Application and Enforcement of Group Health Plan Requirements

SEC. 401. GROUP HEALTH PLAN PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS.

(a) IN GENERAL.—The Internal Revenue Code of 1986 is amended by adding at the end the following new subtitle:

<< 26 USCA Ch. 100 >>

“Subtitle K—Group Health Plan Portability, Access, and Renewability Requirements

“Chapter 100. Group health plan portability, access, and renewability requirements.

“CHAPTER 100—GROUP HEALTH PLAN PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS

“Sec. 9801. Increased portability through limitation on preexisting condition exclusions.

“Sec. 9802. Prohibiting discrimination against individual participants and beneficiaries based on health status.

“Sec. 9803. Guaranteed renewability in multiemployer plans and certain multiple employer welfare arrangements.

“Sec. 9804. General exceptions.

“Sec. 9805. Definitions.

“Sec. 9806. Regulations.

<< 26 USCA § 9801 >>

“SEC. 9801. INCREASED PORTABILITY THROUGH LIMITATION ON PREEXISTING CONDITION EXCLUSIONS.

“(a) LIMITATION ON PREEXISTING CONDITION EXCLUSION PERIOD; CREDITING FOR PERIODS OF PREVIOUS COVERAGE.—Subject to subsection (d), a group health plan may, with respect to a participant or beneficiary, impose a preexisting condition exclusion only if—

“(1) such exclusion relates to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6-month period ending on the enrollment date;

“(2) such exclusion extends for a period of not more than 12 months (or 18 months in the case of a late enrollee) after the enrollment date; and

“(3) the period of any such preexisting condition exclusion is reduced by the length of the aggregate of the periods of creditable coverage (if any) applicable to the participant or beneficiary as of the enrollment date.

“(b) DEFINITIONS.—For purposes of this section—

“(1) PREEXISTING CONDITION EXCLUSION.—

“(A) IN GENERAL.—The term ‘preexisting condition exclusion’ means, with respect to coverage, a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.

“(B) TREATMENT OF GENETIC INFORMATION.—For purposes of this section, genetic information shall not be treated as a condition described in subsection (a)(1) in the absence of a diagnosis of the condition related to such information.

“(2) ENROLLMENT DATE.—The term ‘enrollment date’ means, with respect to an individual covered under a group health plan, the date of enrollment of the individual in the plan or, if earlier, the first day of the waiting period for such enrollment.

“(3) LATE ENROLLEE.—The term ‘late enrollee’ means, with respect to coverage under a group health plan, a participant or beneficiary who enrolls under the plan other than during—

“(A) the first period in which the individual is eligible to enroll under the plan, or

“(B) a special enrollment period under subsection (f).

“(4) WAITING PERIOD.—The term ‘waiting period’ means, with respect to a group health plan and an individual who is a potential participant or beneficiary in the plan, the period that must pass with respect to the individual before the individual is eligible to be covered for benefits under the terms of the plan.

“(c) RULES RELATING TO CREDITING PREVIOUS COVERAGE.—

“(1) CREDITABLE COVERAGE DEFINED.—For purposes of this part, the term ‘creditable coverage’ means, with respect to an individual, coverage of the individual under any of the following:

“(A) A group health plan.

“(B) Health insurance coverage.

“(C) Part A or part B of title XVIII of the Social Security Act.

“(D) Title XIX of the Social Security Act, other than coverage consisting solely of benefits under section 1928.

“(E) Chapter 55 of title 10, United States Code.

“(F) A medical care program of the Indian Health Service or of a tribal organization.

“(G) A State health benefits risk pool.

“(H) A health plan offered under chapter 89 of title 5, United States Code.

“(I) A public health plan (as defined in regulations).

“(J) A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

Such term does not include coverage consisting solely of coverage of excepted benefits (as defined in section 9805(c)).

“(2) NOT COUNTING PERIODS BEFORE SIGNIFICANT BREAKS IN COVERAGE.—

“(A) IN GENERAL.—A period of creditable coverage shall not be counted, with respect to enrollment of an individual under a group health plan, if, after such period and before the enrollment date, there was a 63-day period during all of which the individual was not covered under any creditable coverage.

“(B) WAITING PERIOD NOT TREATED AS A BREAK IN COVERAGE.—For purposes of subparagraph (A) and subsection (d)(4), any period that an individual is in a waiting period for any coverage under a group health plan or is in an affiliation period shall not be taken into account in determining the continuous period under subparagraph (A).

“(C) AFFILIATION PERIOD.—

“(i) IN GENERAL.—For purposes of this section, the term ‘affiliation period’ means a period which, under the terms of the health insurance coverage offered by the health maintenance organization, must expire before the health insurance coverage becomes effective. During such an affiliation period, the organization is not required to provide health care services or benefits and no premium shall be charged to the participant or beneficiary.

“(ii) BEGINNING.—Such period shall begin on the enrollment date.

“(iii) RUNS CONCURRENTLY WITH WAITING PERIODS.—Any such affiliation period shall run concurrently with any waiting period under the plan.

“(3) METHOD OF CREDITING COVERAGE.—

“(A) STANDARD METHOD.—Except as otherwise provided under subparagraph (B), for purposes of applying subsection (a)(3), a group health plan shall count a period of creditable coverage without regard to the specific benefits for which coverage is offered during the period.

“(B) ELECTION OF ALTERNATIVE METHOD.—A group health plan may elect to apply subsection (a)(3) based on coverage of any benefits within each of several classes or categories of benefits specified in regulations rather than as provided under subparagraph (A). Such election shall be made on a uniform basis for all participants and beneficiaries. Under such election a group health plan shall count a period of creditable coverage with respect to any class or category of benefits if any level of benefits is covered within such class or category.

“(C) PLAN NOTICE.—In the case of an election with respect to a group health plan under subparagraph (B), the plan shall—

“(i) prominently state in any disclosure statements concerning the plan, and state to each enrollee at the time of enrollment under the plan, that the plan has made such election, and

“(ii) include in such statements a description of the effect of this election.

“(4) ESTABLISHMENT OF PERIOD.—Periods of creditable coverage with respect to an individual shall be established through presentation of certifications described in subsection (e) or in such other manner as may be specified in regulations.

“(d) EXCEPTIONS.—

“(1) EXCLUSION NOT APPLICABLE TO CERTAIN NEWBORNS.—Subject to paragraph (4), a group health plan may not impose any preexisting condition exclusion in the case of an individual who, as of the last day of the 30-day period beginning with the date of birth, is covered under creditable coverage.

“(2) EXCLUSION NOT APPLICABLE TO CERTAIN ADOPTED CHILDREN.—Subject to paragraph (4), a group health plan may not impose any preexisting condition exclusion in the case of a child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30-day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. The previous sentence shall not apply to coverage before the date of such adoption or placement for adoption.

“(3) EXCLUSION NOT APPLICABLE TO PREGNANCY.—For purposes of this section, a group health plan may not impose any preexisting condition exclusion relating to pregnancy as a preexisting condition.

“(4) LOSS IF BREAK IN COVERAGE.—Paragraphs (1) and (2) shall no longer apply to an individual after the end of the first 63-day period during all of which the individual was not covered under any creditable coverage.

“(e) CERTIFICATIONS AND DISCLOSURE OF COVERAGE.—

“(1) REQUIREMENT FOR CERTIFICATION OF PERIOD OF CREDITABLE COVERAGE.—

“(A) IN GENERAL.—A group health plan shall provide the certification described in subparagraph (B)—

“(i) at the time an individual ceases to be covered under the plan or otherwise becomes covered under a COBRA continuation provision,

“(ii) in the case of an individual becoming covered under such a provision, at the time the individual ceases to be covered under such provision, and

“(iii) on the request on behalf of an individual made not later than 24 months after the date of cessation of the coverage described in clause (i) or (ii), whichever is later.

The certification under clause (i) may be provided, to the extent practicable, at a time consistent with notices required under any applicable COBRA continuation provision.

“(B) CERTIFICATION.—The certification described in this subparagraph is a written certification of—

“(i) the period of creditable coverage of the individual under such plan and the coverage under such COBRA continuation provision, and

“(ii) the waiting period (if any) (and affiliation period, if applicable) imposed with respect to the individual for any coverage under such plan.

“(C) ISSUER COMPLIANCE.—To the extent that medical care under a group health plan consists of health insurance coverage offered in connection with the plan, the plan is deemed to have satisfied the certification requirement under this paragraph if the issuer provides for such certification in accordance with this paragraph.

“(2) DISCLOSURE OF INFORMATION ON PREVIOUS BENEFITS.—

“(A) IN GENERAL.—In the case of an election described in subsection (c)(3)(B) by a group health plan, if the plan enrolls an individual for coverage under the plan and the individual provides a certification of coverage of the individual under paragraph (1)—

“(i) upon request of such plan, the entity which issued the certification provided by the individual shall promptly disclose to such requesting plan information on coverage of classes and categories of health benefits available under such entity's plan, and

“(ii) such entity may charge the requesting plan or issuer for the reasonable cost of disclosing such information.

“(3) REGULATIONS.—The Secretary shall establish rules to prevent an entity's failure to provide information under paragraph (1) or (2) with respect to previous coverage of an individual from adversely affecting any subsequent coverage of the individual under another group health plan or health insurance coverage.

“(f) SPECIAL ENROLLMENT PERIODS.—

“(1) INDIVIDUALS LOSING OTHER COVERAGE.—A group health plan shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if each of the following conditions is met:

“(A) The employee or dependent was covered under a group health plan or had health insurance coverage at the time coverage was previously offered to the employee or individual.

“(B) The employee stated in writing at such time that coverage under a group health plan or health insurance coverage was the reason for declining enrollment, but only if the plan sponsor (or the health insurance issuer offering health insurance coverage in connection with the plan) required such a statement at such time and provided the employee with notice of such requirement (and the consequences of such requirement) at such time.

“(C) The employee's or dependent's coverage described in subparagraph (A)—

“(i) was under a COBRA continuation provision and the coverage under such provision was exhausted; or

“(ii) was not under such a provision and either the coverage was terminated as a result of loss of eligibility for the coverage (including as a result of legal separation, divorce, death, termination of employment, or reduction in the number of hours of employment) or employer contributions toward such coverage were terminated.

“(D) Under the terms of the plan, the employee requests such enrollment not later than 30 days after the date of exhaustion of coverage described in subparagraph (C)(i) or termination of coverage or employer contribution described in subparagraph (C)(ii).

“(2) FOR DEPENDENT BENEFICIARIES.—

“(A) IN GENERAL.—If—

“(i) a group health plan makes coverage available with respect to a dependent of an individual,

“(ii) the individual is a participant under the plan (or has met any waiting period applicable to becoming a participant under the plan and is eligible to be enrolled under the plan but for a failure to enroll during a previous enrollment period), and

“(iii) a person becomes such a dependent of the individual through marriage, birth, or adoption or placement for adoption, the group health plan shall provide for a dependent special enrollment period described in subparagraph (B) during which the person (or, if not otherwise enrolled, the individual) may be enrolled under the plan as a dependent of the individual, and in the case of the birth or adoption of a child, the spouse of the individual may be enrolled as a dependent of the individual if such spouse is otherwise eligible for coverage.

“(B) DEPENDENT SPECIAL ENROLLMENT PERIOD.—The dependent special enrollment period under this subparagraph shall be a period of not less than 30 days and shall begin on the later of—

“(i) the date dependent coverage is made available, or

“(ii) the date of the marriage, birth, or adoption or placement for adoption (as the case may be) described in subparagraph (A)(iii).

“(C) NO WAITING PERIOD.—If an individual seeks coverage of a dependent during the first 30 days of such a dependent special enrollment period, the coverage of the dependent shall become effective—

“(i) in the case of marriage, not later than the first day of the first month beginning after the date the completed request for enrollment is received;

“(ii) in the case of a dependent's birth, as of the date of such birth; or

“(iii) in the case of a dependent's adoption or placement for adoption, the date of such adoption or placement for adoption.

<< 26 USCA § 9802 >>

“SEC. 9802. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

“(a) IN ELIGIBILITY TO ENROLL.—

“(1) IN GENERAL.—Subject to paragraph (2), a group health plan may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following factors in relation to the individual or a dependent of the individual:

“(A) Health status.

“(B) Medical condition (including both physical and mental illnesses).

“(C) Claims experience.

“(D) Receipt of health care.

“(E) Medical history.

“(F) Genetic information.

“(G) Evidence of insurability (including conditions arising out of acts of domestic violence).

“(H) Disability.

“(2) NO APPLICATION TO BENEFITS OR EXCLUSIONS.—To the extent consistent with section 9801, paragraph (1) shall not be construed—

“(A) to require a group health plan to provide particular benefits (or benefits with respect to a specific procedure, treatment, or service) other than those provided under the terms of such plan; or

“(B) to prevent such a plan from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

“(3) CONSTRUCTION.—For purposes of paragraph (1), rules for eligibility to enroll under a plan include rules defining any applicable waiting periods for such enrollment.

“(b) IN PREMIUM CONTRIBUTIONS.—

“(1) IN GENERAL.—A group health plan may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any factor described in subsection (a)(1) in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

“(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

“(A) to restrict the amount that an employer may be charged for coverage under a group health plan; or

“(B) to prevent a group health plan from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

<< 26 USCA § 9803 >>

“SEC. 9803. GUARANTEED RENEWABILITY IN MULTIEMPLOYER PLANS AND CERTAIN MULTIPLE EMPLOYER WELFARE ARRANGEMENTS.

“(a) IN GENERAL.—A group health plan which is a multiemployer plan (as defined in section 414(f)) or which is a multiple employer welfare arrangement may not deny an employer continued access to the same or different coverage under such plan, other than—

“(1) for nonpayment of contributions;

“(2) for fraud or other intentional misrepresentation of material fact by the employer;

“(3) for noncompliance with material plan provisions;

“(4) because the plan is ceasing to offer any coverage in a geographic area;

“(5) in the case of a plan that offers benefits through a network plan, because there is no longer any individual enrolled through the employer who lives, resides, or works in the service area of the network plan and the plan applies this paragraph uniformly without regard to the claims experience of employers or a factor described in section 9802(a)(1) in relation to such individuals or their dependents; or

“(6) for failure to meet the terms of an applicable collective bargaining agreement, to renew a collective bargaining or other agreement requiring or authorizing contributions to the plan, or to employ employees covered by such an agreement.

“(b) MULTIPLE EMPLOYER WELFARE ARRANGEMENT.—For purposes of subsection (a), the term ‘multiple employer welfare arrangement’ has the meaning given such term by section 3(40) of the Employee Retirement Income Security Act of 1974, as in effect on the date of the enactment of this section.

<< 26 USCA § 9804 >>

“SEC. 9804. GENERAL EXCEPTIONS.

“(a) EXCEPTION FOR CERTAIN PLANS.—The requirements of this chapter shall not apply to—

“(1) any governmental plan, and

“(2) any group health plan for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees.

“(b) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of this chapter shall not apply to any group health plan in relation to its provision of excepted benefits described in section 9805(c)(1).

“(c) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—

“(1) LIMITED, EXCEPTED BENEFITS.—The requirements of this chapter shall not apply to any group health plan in relation to its provision of excepted benefits described in section 9805(c)(2) if the benefits—

“(A) are provided under a separate policy, certificate, or contract of insurance; or

“(B) are otherwise not an integral part of the plan.

“(2) NONCOORDINATED, EXCEPTED BENEFITS.—The requirements of this chapter shall not apply to any group health plan in relation to its provision of excepted benefits described in section 9805(c)(3) if all of the following conditions are met:

“(A) The benefits are provided under a separate policy, certificate, or contract of insurance.

“(B) There is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor.

“(C) Such benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor.

“(3) SUPPLEMENTAL EXCEPTED BENEFITS.—The requirements of this chapter shall not apply to any group health plan in relation to its provision of excepted benefits described in section 9805(c)(4) if the benefits are provided under a separate policy, certificate, or contract of insurance.

<< 26 USCA § 9805 >>

“SEC. 9805. DEFINITIONS.

“(a) GROUP HEALTH PLAN.—For purposes of this chapter, the term ‘group health plan’ has the meaning given to such term by section 5000(b)(1).

“(b) DEFINITIONS RELATING TO HEALTH INSURANCE.—For purposes of this chapter—

“(1) HEALTH INSURANCE COVERAGE.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), the term ‘health insurance coverage’ means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer.

“(B) NO APPLICATION TO CERTAIN EXCEPTED BENEFITS.—In applying subparagraph (A), excepted benefits described in subsection (c)(1) shall not be treated as benefits consisting of medical care.

“(2) HEALTH INSURANCE ISSUER.—The term ‘health insurance issuer’ means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in paragraph (3)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974, as in effect on the date of the enactment of this section). Such term does not include a group health plan.

“(3) HEALTH MAINTENANCE ORGANIZATION.—The term ‘health maintenance organization’ means—

“(A) a federally qualified health maintenance organization (as defined in section 1301(a) of the Public Health Service Act (42 U.S.C. 300e(a))),

“(B) an organization recognized under State law as a health maintenance organization, or

“(C) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

“(c) EXCEPTED BENEFITS.—For purposes of this chapter, the term ‘excepted benefits’ means benefits under one or more (or any combination thereof) of the following:

“(1) BENEFITS NOT SUBJECT TO REQUIREMENTS.—

“(A) Coverage only for accident, or disability income insurance, or any combination thereof.

“(B) Coverage issued as a supplement to liability insurance.

“(C) Liability insurance, including general liability insurance and automobile liability insurance.

“(D) Workers’ compensation or similar insurance.

“(E) Automobile medical payment insurance.

“(F) Credit-only insurance.

“(G) Coverage for on-site medical clinics.

“(H) Other similar insurance coverage, specified in regulations, under which benefits for medical care are secondary or incidental to other insurance benefits.

“(2) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED SEPARATELY.—

“(A) Limited scope dental or vision benefits.

“(B) Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof.

“(C) Such other similar, limited benefits as are specified in regulations.

“(3) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS INDEPENDENT, NONCOORDINATED BENEFITS.—

“(A) Coverage only for a specified disease or illness.

“(B) Hospital indemnity or other fixed indemnity insurance.

“(4) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS SEPARATE INSURANCE POLICY.—Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act), coverage supplemental to the coverage provided under chapter 55 of title 10, United States Code, and similar supplemental coverage provided to coverage under a group health plan.

“(d) OTHER DEFINITIONS.—For purposes of this chapter—

“(1) COBRA CONTINUATION PROVISION.—The term ‘COBRA continuation provision’ means any of the following:

“(A) Section 4980B, other than subsection (f)(1) thereof insofar as it relates to pediatric vaccines.

“(B) Part 6 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1161 et seq.), other than section 609 of such Act.

“(C) Title XXII of the Public Health Service Act.

“(2) GOVERNMENTAL PLAN.—The term ‘governmental plan’ has the meaning given such term by section 414(d).

“(3) MEDICAL CARE.—The term ‘medical care’ has the meaning given such term by section 213(d) determined without regard to—

“(A) paragraph (1)(C) thereof, and

“(B) so much of paragraph (1)(D) thereof as relates to qualified long-term care insurance.

“(4) NETWORK PLAN.—The term ‘network plan’ means health insurance coverage of a health insurance issuer under which the financing and delivery of medical care are provided, in whole or in part, through a defined set of providers under contract with the issuer.

“(5) PLACED FOR ADOPTION DEFINED.—The term ‘placement’, or being ‘placed’, for adoption, in connection with any placement for adoption of a child with any person, means the assumption and retention by such person of a legal obligation for total or partial support of such child in anticipation of adoption of such child. The child's placement with such person terminates upon the termination of such legal obligation.

<< 26 USCA § 9806 >>

“SEC. 9806. REGULATIONS.

“The Secretary, consistent with section 104 of the Health Care Portability and Accountability Act of 1996, may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this chapter. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this chapter.”.

<< 26 USCA Ch. 1 >>

(b) CLERICAL AMENDMENT.—The table of subtitles of such Code is amended by adding at the end the following new item:

“Subtitle K. Group health plan portability, access, and renewability requirements.”.

<< 26 USCA §§ 9801 NOTE, 9802 nt, 9803 nt, 9804 nt, 9805 nt, 9806 nt >>

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to plan years beginning after June 30, 1997.

(2) DETERMINATION OF CREDITABLE COVERAGE.—

(A) PERIOD OF COVERAGE.—

(i) IN GENERAL.—Subject to clause (ii), no period before July 1, 1996, shall be taken into account under chapter 100 of the Internal Revenue Code of 1986 (as added by this section) in determining creditable coverage.

(ii) SPECIAL RULE FOR CERTAIN PERIODS.—The Secretary of the Treasury, consistent with section 104, shall provide for a process whereby individuals who need to establish creditable coverage for periods before July 1, 1996, and who would have such coverage credited but for clause (i) may be given credit for creditable coverage for such periods through the presentation of documents or other means.

(B) CERTIFICATIONS, ETC.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), subsection (e) of section 9801 of the Internal Revenue Code of 1986 (as added by this section) shall apply to events occurring after June 30, 1996.

(ii) NO CERTIFICATION REQUIRED TO BE PROVIDED BEFORE JUNE 1, 1997.—In no case is a certification required to be provided under such subsection before June 1, 1997.

(iii) CERTIFICATION ONLY ON WRITTEN REQUEST FOR EVENTS OCCURRING BEFORE OCTOBER 1, 1996.—In the case of an event occurring after June 30, 1996, and before October 1, 1996, a certification is not required to be provided under such subsection unless an individual (with respect to whom the certification is otherwise required to be made) requests such certification in writing.

(C) TRANSITIONAL RULE.—In the case of an individual who seeks to establish creditable coverage for any period for which certification is not required because it relates to an event occurring before June 30, 1996—

(i) the individual may present other credible evidence of such coverage in order to establish the period of creditable coverage; and

(ii) a group health plan and a health insurance issuer shall not be subject to any penalty or enforcement action with respect to the plan's or issuer's crediting (or not crediting) such coverage if the plan or issuer has sought to comply in good faith with the applicable requirements under the amendments made by this section.

(3) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—Except as provided in paragraph (2), in the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, the amendments made by this section shall not apply to plan years beginning before the later of—

(A) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act), or

(B) July 1, 1997.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this section shall not be treated as a termination of such collective bargaining agreement.

(4) TIMELY REGULATIONS.—The Secretary of the Treasury, consistent with section 104, shall first issue by not later than April 1, 1997, such regulations as may be necessary to carry out the amendments made by this section.

(5) LIMITATION ON ACTIONS.—No enforcement action shall be taken, pursuant to the amendments made by this section, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by such amendments before January 1, 1998, or, if later, the date of issuance of regulations referred to in paragraph (4), if the plan or issuer has sought to comply in good faith with such requirements.

SEC. 402. PENALTY ON FAILURE TO MEET CERTAIN GROUP HEALTH PLAN REQUIREMENTS.

<< 26 USCA § 4980D >>

(a) IN GENERAL.—Chapter 43 of the Internal Revenue Code of 1986 (relating to qualified pension, etc., plans) is amended by adding after section 4980C the following new section:

“SEC. 4980D. FAILURE TO MEET CERTAIN GROUP HEALTH PLAN REQUIREMENTS.

“(a) GENERAL RULE.—There is hereby imposed a tax on any failure of a group health plan to meet the requirements of chapter 100 (relating to group health plan portability, access, and renewability requirements).

“(b) AMOUNT OF TAX.—

“(1) IN GENERAL.—The amount of the tax imposed by subsection (a) on any failure shall be \$100 for each day in the noncompliance period with respect to each individual to whom such failure relates.

“(2) NONCOMPLIANCE PERIOD.—For purposes of this section, the term ‘noncompliance period’ means, with respect to any failure, the period—

“(A) beginning on the date such failure first occurs, and

“(B) ending on the date such failure is corrected.

“(3) MINIMUM TAX FOR NONCOMPLIANCE PERIOD WHERE FAILURE DISCOVERED AFTER NOTICE OF EXAMINATION.—Notwithstanding paragraphs (1) and (2) of subsection (c)—

“(A) IN GENERAL.—In the case of 1 or more failures with respect to an individual—

“(i) which are not corrected before the date a notice of examination of income tax liability is sent to the employer, and

“(ii) which occurred or continued during the period under examination,

the amount of tax imposed by subsection (a) by reason of such failures with respect to such individual shall not be less than the lesser of \$2,500 or the amount of tax which would be imposed by subsection (a) without regard to such paragraphs.

“(B) HIGHER MINIMUM TAX WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.—To the extent violations for which any person is liable under subsection (e) for any year are more than de minimis, subparagraph (A) shall be applied by substituting ‘\$15,000’ for ‘\$2,500’ with respect to such person.

“(C) EXCEPTION FOR CHURCH PLANS.—This paragraph shall not apply to any failure under a church plan (as defined in section 414(e)).

“(c) LIMITATIONS ON AMOUNT OF TAX.—

“(1) TAX NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No tax shall be imposed by subsection (a) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such tax did not know, and exercising reasonable diligence would not have known, that such failure existed.

“(2) TAX NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No tax shall be imposed by subsection (a) on any failure if—

“(A) such failure was due to reasonable cause and not to willful neglect, and

“(B)(i) in the case of a plan other than a church plan (as defined in section 414(e)), such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such tax knew, or exercising reasonable diligence would have known, that such failure existed, and

“(ii) in the case of a church plan (as so defined), such failure is corrected before the close of the correction period (determined under the rules of section 414(e)(4)(C)).

“(3) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect—

“(A) SINGLE EMPLOYER PLANS.—

“(i) IN GENERAL.—In the case of failures with respect to plans other than specified multiple employer health plans, the tax imposed by subsection (a) for failures during the taxable year of the employer shall not exceed the amount equal to the lesser of—

“(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans, or

“(II) \$500,000.

“(ii) TAXABLE YEARS IN THE CASE OF CERTAIN CONTROLLED GROUPS.—For purposes of this subparagraph, if not all persons who are treated as a single employer for purposes of this section have the same taxable year, the taxable years taken into account shall be determined under principles similar to the principles of section 1561.

“(B) SPECIFIED MULTIPLE EMPLOYER HEALTH PLANS.—

“(i) IN GENERAL.—In the case of failures with respect to a specified multiple employer health plan, the tax imposed by subsection (a) for failures during the taxable year of the trust forming part of such plan shall not exceed the amount equal to the lesser of—

“(I) 10 percent of the amount paid or incurred by such trust during such taxable year to provide medical care (as defined in section 9805(d)(3)) directly or through insurance, reimbursement, or otherwise, or

“(II) \$500,000.

For purposes of the preceding sentence, all plans of which the same trust forms a part shall be treated as one plan.

“(ii) SPECIAL RULE FOR EMPLOYERS REQUIRED TO PAY TAX.—If an employer is assessed a tax imposed by subsection (a) by reason of a failure with respect to a specified multiple employer health plan, the limit shall be determined under subparagraph (A) (and not under this subparagraph) and as if such plan were not a specified multiple employer health plan.

“(4) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the tax imposed by subsection (a) to the extent that the payment of such tax would be excessive relative to the failure involved.

“(d) TAX NOT TO APPLY TO CERTAIN INSURED SMALL EMPLOYER PLANS.—

“(1) IN GENERAL.—In the case of a group health plan of a small employer which provides health insurance coverage solely through a contract with a health insurance issuer, no tax shall be imposed by this section on the employer on any failure which is solely because of the health insurance coverage offered by such issuer.

“(2) SMALL EMPLOYER.—

“(A) IN GENERAL.—For purposes of paragraph (1), the term ‘small employer’ means, with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year. For purposes of the preceding sentence, all persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 shall be treated as one employer.

“(B) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence throughout the preceding calendar year, the determination of whether such employer is a small employer shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

“(C) PREDECESSORS.—Any reference in this paragraph to an employer shall include a reference to any predecessor of such employer.

“(3) HEALTH INSURANCE COVERAGE; HEALTH INSURANCE ISSUER.—For purposes of paragraph (1), the terms ‘health insurance coverage’ and ‘health insurance issuer’ have the respective meanings given such terms by section 9805.

“(e) LIABILITY FOR TAX.—The following shall be liable for the tax imposed by subsection (a) on a failure:

“(1) Except as otherwise provided in this subsection, the employer.

“(2) In the case of a multiemployer plan, the plan.

“(3) In the case of a failure under section 9803 (relating to guaranteed renewability) with respect to a plan described in subsection (f)(2)(B), the plan.

“(f) DEFINITIONS.—For purposes of this section—

“(1) GROUP HEALTH PLAN.—The term ‘group health plan’ has the meaning given such term by section 9805(a).

“(2) SPECIFIED MULTIPLE EMPLOYER HEALTH PLAN.—The term ‘specified multiple employer health plan’ means a group health plan which is—

“(A) any multiemployer plan, or

“(B) any multiple employer welfare arrangement (as defined in section 3(40) of the Employee Retirement Income Security Act of 1974, as in effect on the date of the enactment of this section).

“(3) CORRECTION.—A failure of a group health plan shall be treated as corrected if—

“(A) such failure is retroactively undone to the extent possible, and

“(B) the person to whom the failure relates is placed in a financial position which is as good as such person would have been in had such failure not occurred.”.

<< 26 USCA Ch. 43 >>

(b) CLERICAL AMENDMENT.—The table of sections for chapter 43 of such Code is amended by adding after the item relating to section 4980C the following new item:

“Sec. 4980D. Failure to meet certain group health plan requirements.”.

<< 26 USCA § 4980D NOTE >>

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to failures under chapter 100 of the Internal Revenue Code of 1986 (as added by section 401 of this Act).

Subtitle B—Clarification of Certain Continuation Coverage Requirements

SEC. 421. COBRA CLARIFICATIONS.

(a) PUBLIC HEALTH SERVICE ACT.—

<< 42 USCA § 300bb-2 >>

(1) PERIOD OF COVERAGE.—Section 2202(2) of the Public Health Service Act (42 U.S.C. 300bb-2(2)) is amended—

(A) in subparagraph (A)—

(i) by transferring the sentence immediately preceding clause (iv) so as to appear immediately following such clause (iv); and

(ii) in the last sentence (as so transferred)—

(I) by striking “an individual” and inserting “a qualified beneficiary”;

(II) by striking “at the time of a qualifying event described in section 2203(2)” and inserting “at any time during the first 60 days of continuation coverage under this title”;

(III) by striking “with respect to such event,”; and

(IV) by inserting “(with respect to all qualified beneficiaries)” after “29 months”;

(B) in subparagraph (D)(i), by inserting before “, or” the following: “(other than such an exclusion or limitation which does not apply to (or is satisfied by) such beneficiary by reason of chapter 100 of the Internal Revenue Code of 1986, part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, or title XXVII of this Act)”;

(C) in subparagraph (E), by striking “at the time of a qualifying event described in section 2203(2)” and inserting “at any time during the first 60 days of continuation coverage under this title”.

<< 42 USCA § 300bb-6 >>

(2) NOTICES.—Section 2206(3) of the Public Health Service Act (42 U.S.C. 300bb-6(3)) is amended by striking “at the time of a qualifying event described in section 2203(2)” and inserting “at any time during the first 60 days of continuation coverage under this title”.

<< 42 USCA § 300bb-8 >>

(3) BIRTH OR ADOPTION OF A CHILD.—Section 2208(3)(A) of the Public Health Service Act (42 U.S.C. 300bb-8(3)(A)) is amended by adding at the end thereof the following new flush sentence:

“Such term shall also include a child who is born to or placed for adoption with the covered employee during the period of continuation coverage under this title.”.

(b) EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

<< 29 USCA § 1162 >>

(1) PERIOD OF COVERAGE.—Section 602(2) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1162(2)) is amended—

(A) in the last sentence of subparagraph (A)—

(i) by striking “an individual” and inserting “a qualified beneficiary”;

(ii) by striking “at the time of a qualifying event described in section 603(2)” and inserting “at any time during the first 60 days of continuation coverage under this part”;

(iii) by striking “with respect to such event”; and

(iv) by inserting “(with respect to all qualified beneficiaries)” after “29 months”;

(B) in subparagraph (D)(i), by inserting before “, or” the following: “(other than such an exclusion or limitation which does not apply to (or is satisfied by) such beneficiary by reason of chapter 100 of the Internal Revenue Code of 1986, part 7 of this subtitle, or title XXVII of the Public Health Service Act)”;

(C) in subparagraph (E), by striking “at the time of a qualifying event described in section 603(2)” and inserting “at any time during the first 60 days of continuation coverage under this part”.

<< 29 USCA § 1166 >>

(2) NOTICES.—Section 606(a)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1166(a)(3)) is amended by striking “at the time of a qualifying event described in section 603(2)” and inserting “at any time during the first 60 days of continuation coverage under this part”.

<< 29 USCA § 1167 >>

(3) BIRTH OR ADOPTION OF A CHILD.—Section 607(3)(A) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1167(3)) is amended by adding at the end thereof the following new flush sentence:

“Such term shall also include a child who is born to or placed for adoption with the covered employee during the period of continuation coverage under this part.”.

<< 26 USCA § 4980B >>

(c) INTERNAL REVENUE CODE OF 1986.—

(1) PERIOD OF COVERAGE.—Section 4980B(f)(2)(B) of the Internal Revenue Code of 1986 is amended—

(A) in the last sentence of clause (i)—

(i) by striking “at the time of a qualifying event described in paragraph (3)(B)” and inserting “at any time during the first 60 days of continuation coverage under this section”;

(ii) by striking “with respect to such event”; and

(iii) by inserting “(with respect to all qualified beneficiaries)” after “29 months”;

(B) in clause (iv)(I), by inserting before “, or” the following: “(other than such an exclusion or limitation which does not apply to (or is satisfied by) such beneficiary by reason of chapter 100 of this title, part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, or title XXVII of the Public Health Service Act)”; and

(C) in clause (v), by striking “at the time of a qualifying event described in paragraph (3)(B)” and inserting “at any time during the first 60 days of continuation coverage under this section”.

(2) NOTICES.—Section 4980B(f)(6)(C) of the Internal Revenue Code of 1986 is amended by striking “at the time of a qualifying event described in paragraph (3)(B)” and inserting “at any time during the first 60 days of continuation coverage under this section”.

(3) BIRTH OR ADOPTION OF A CHILD.—Section 4980B(g)(1)(A) of the Internal Revenue Code of 1986 is amended by adding at the end thereof the following new flush sentence:

“Such term shall also include a child who is born to or placed for adoption with the covered employee during the period of continuation coverage under this section.”.

<< 26 USCA § 4980B NOTE >>

<< 29 USCA §§ 1162 nt, 1166 nt, 1167 nt >>

<< 42 USCA §§ 300bb-2 nt, 300bb-6 nt, 300bb-8 nt >>

(d) EFFECTIVE DATE.—The amendments made by this section shall become effective on January 1, 1997, regardless of whether the qualifying event occurred before, on, or after such date.

<< 26 USCA § 4980B NOTE >>

(e) NOTIFICATION OF CHANGES.—Not later than November 1, 1996, each group health plan (covered under title XXII of the Public Health Service Act, part 6 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, and section 4980B(f) of the Internal Revenue Code of 1986) shall notify each qualified beneficiary who has elected continuation coverage under such title, part or section of the amendments made by this section.

TITLE V—REVENUE OFFSETS

SEC. 500. AMENDMENT OF 1986 CODE.

Except as otherwise expressly provided, whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Internal Revenue Code of 1986.

Subtitle A—Company-Owned Life Insurance

SEC. 501. DENIAL OF DEDUCTION FOR INTEREST ON LOANS WITH RESPECT TO COMPANY-OWNED LIFE INSURANCE.

<< 26 USCA § 264 >>

(a) IN GENERAL.—Paragraph (4) of section 264(a) is amended—

(1) by inserting “, or any endowment or annuity contracts owned by the taxpayer covering any individual,” after “the life of any individual”, and

(2) by striking all that follows “carried on by the taxpayer” and inserting a period.

(b) EXCEPTION FOR CONTRACTS RELATING TO KEY PERSONS; PERMISSIBLE INTEREST RATES.—Section 264 is amended—

(1) by striking “Any” in subsection (a)(4) and inserting “Except as provided in subsection (d), any”, and

(2) by adding at the end the following new subsection:

“(d) SPECIAL RULES FOR APPLICATION OF SUBSECTION (a)(4).—

“(1) EXCEPTION FOR KEY PERSONS.—Subsection (a)(4) shall not apply to any interest paid or accrued on any indebtedness with respect to policies or contracts covering an individual who is a key person to the extent that the aggregate amount of such indebtedness with respect to policies and contracts covering such individual does not exceed \$50,000.

“(2) INTEREST RATE CAP ON KEY PERSONS AND PRE-1986 CONTRACTS.—

“(A) IN GENERAL.—No deduction shall be allowed by reason of paragraph (1) or the last sentence of subsection (a) with respect to interest paid or accrued for any month beginning after December 31, 1995, to the extent the amount of such interest exceeds the amount which would have been determined if the applicable rate of interest were used for such month.

“(B) APPLICABLE RATE OF INTEREST.—For purposes of subparagraph (A)—

“(i) IN GENERAL.—The applicable rate of interest for any month is the rate of interest described as Moody's Corporate Bond Yield Average—Monthly Average Corporates as published by Moody's Investors Service, Inc., or any successor thereto, for such month.

“(ii) PRE-1986 CONTRACTS.—In the case of indebtedness on a contract purchased on or before June 20, 1986—

“(I) which is a contract providing a fixed rate of interest, the applicable rate of interest for any month shall be the Moody's rate described in clause (i) for the month in which the contract was purchased, or

“(II) which is a contract providing a variable rate of interest, the applicable rate of interest for any month in an applicable period shall be such Moody's rate for the third month preceding the first month in such period.

For purposes of subclause (II), the taxpayer shall elect an applicable period for such contract on its return of tax imposed by this chapter for its first taxable year ending on or after October 13, 1995. Such applicable period shall be for any number of months (not greater than 12) specified in the election and may not be changed by the taxpayer without the consent of the Secretary.

“(3) KEY PERSON.—For purposes of paragraph (1), the term ‘key person’ means an officer or 20-percent owner, except that the number of individuals who may be treated as key persons with respect to any taxpayer shall not exceed the greater of—

“(A) 5 individuals, or

“(B) the lesser of 5 percent of the total officers and employees of the taxpayer or 20 individuals.

“(4) 20-PERCENT OWNER.—For purposes of this subsection, the term ‘20-percent owner’ means—

“(A) if the taxpayer is a corporation, any person who owns directly 20 percent or more of the outstanding stock of the corporation or stock possessing 20 percent or more of the total combined voting power of all stock of the corporation, or
“(B) if the taxpayer is not a corporation, any person who owns 20 percent or more of the capital or profits interest in the employer.

“(5) AGGREGATION RULES.—

“(A) IN GENERAL.—For purposes of paragraph (4)(A) and applying the \$50,000 limitation in paragraph (1)—

“(i) all members of a controlled group shall be treated as one taxpayer, and

“(ii) such limitation shall be allocated among the members of such group in such manner as the Secretary may prescribe.

“(B) CONTROLLED GROUP.—For purposes of this paragraph, all persons treated as a single employer under subsection (a) or (b) of section 52 or subsection (m) or (o) of section 414 shall be treated as members of a controlled group.”.

<< 26 USCA § 264 NOTE >>

(c) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by this section shall apply to interest paid or accrued after October 13, 1995.

(2) TRANSITION RULE FOR EXISTING INDEBTEDNESS.—

(A) IN GENERAL.—In the case of—

(i) indebtedness incurred before January 1, 1996, or

(ii) indebtedness incurred before January 1, 1997 with respect to any contract or policy entered into in 1994 or 1995,

the amendments made by this section shall not apply to qualified interest paid or accrued on such indebtedness after October 13, 1995, and before January 1, 1999.

(B) QUALIFIED INTEREST.—For purposes of subparagraph (A), the qualified interest with respect to any indebtedness for any month is the amount of interest (otherwise deductible) which would be paid or accrued for such month on such indebtedness if—

(i) in the case of any interest paid or accrued after December 31, 1995, indebtedness with respect to no more than 20,000 insured individuals were taken into account, and

(ii) the lesser of the following rates of interest were used for such month:

(I) The rate of interest specified under the terms of the indebtedness as in effect on October 13, 1995 (and without regard to modification of such terms after such date).

(II) The applicable percentage of the rate of interest described as Moody's Corporate Bond Yield Average-Monthly Average Corporates as published by Moody's Investors Service, Inc., or any successor thereto, for such month.

For purposes of clause (i), all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 or subsection (m) or (o) of section 414 of such Code shall be treated as 1 person. Subclause (II) of clause (ii) shall not apply to any month before January 1, 1996.

(C) APPLICABLE PERCENTAGE.—For purposes of subparagraph (B), the applicable percentage is as follows:

For calendar year:	The percentage is:
1996.....	100 percent
1997.....	90 percent
1998.....	80 percent.

(3) SPECIAL RULE FOR GRANDFATHERED CONTRACTS.—This section shall not apply to any contract purchased on or before June 20, 1986, except that section 264(d)(2) of the Internal Revenue Code of 1986 shall apply to interest paid or accrued after October 13, 1995.

<< 26 USCA § 264 NOTE >>

(d) SPREAD OF INCOME INCLUSION ON SURRENDER, ETC. OF CONTRACTS.—

(1) IN GENERAL.—If any amount is received under any life insurance policy or endowment or annuity contract described in paragraph (4) of section 264(a) of the Internal Revenue Code of 1986—

(A) on the complete surrender, redemption, or maturity of such policy or contract during calendar year 1996, 1997, or 1998, or

(B) in full discharge during any such calendar year of the obligation under the policy or contract which is in the nature of a refund of the consideration paid for the policy or contract,

then (in lieu of any other inclusion in gross income) such amount shall be includible in gross income ratably over the 4-taxable year period beginning with the taxable year such amount would (but for this paragraph) be includible. The preceding sentence shall only apply to the extent the amount is includible in gross income for the taxable year in which the event described in subparagraph (A) or (B) occurs.

(2) SPECIAL RULES FOR APPLYING SECTION 264.—A contract shall not be treated as—

(A) failing to meet the requirement of section 264(c)(1) of the Internal Revenue Code of 1986, or

(B) a single premium contract under section 264(b)(1) of such Code,

solely by reason of an occurrence described in subparagraph (A) or (B) of paragraph (1) of this subsection or solely by reason of no additional premiums being received under the contract by reason of a lapse occurring after October 13, 1995.

(3) SPECIAL RULE FOR DEFERRED ACQUISITION COSTS.—In the case of the occurrence of any event described in subparagraph (A) or (B) of paragraph (1) of this subsection with respect to any policy or contract—

(A) section 848 of the Internal Revenue Code of 1986 shall not apply to the unamortized balance (if any) of the specified policy acquisition expenses attributable to such policy or contract immediately before the insurance company's taxable year in which such event occurs, and

(B) there shall be allowed as a deduction to such company for such taxable year under chapter 1 of such Code an amount equal to such unamortized balance.

Subtitle B—Treatment of Individuals Who Lose United States Citizenship

SEC. 511. REVISION OF INCOME, ESTATE, AND GIFT TAXES ON INDIVIDUALS WHO LOSE UNITED STATES CITIZENSHIP.

<< 26 USCA § 877 >>

(a) IN GENERAL.—Subsection (a) of section 877 is amended to read as follows:

“(a) TREATMENT OF EXPATRIATES.—

“(1) IN GENERAL.—Every nonresident alien individual who, within the 10-year period immediately preceding the close of the taxable year, lost United States citizenship, unless such loss did not have for one of its principal purposes the avoidance of taxes under this subtitle or subtitle B, shall be taxable for such taxable year in the manner provided in subsection (b) if the tax imposed pursuant to such subsection exceeds the tax which, without regard to this section, is imposed pursuant to section 871.

“(2) CERTAIN INDIVIDUALS TREATED AS HAVING TAX AVOIDANCE PURPOSE.—For purposes of paragraph (1), an individual shall be treated as having a principal purpose to avoid such taxes if—

“(A) the average annual net income tax (as defined in section 38(c)(1)) of such individual for the period of 5 taxable years ending before the date of the loss of United States citizenship is greater than \$100,000, or

“(B) the net worth of the individual as of such date is \$500,000 or more.

In the case of the loss of United States citizenship in any calendar year after 1996, such \$100,000 and \$500,000 amounts shall be increased by an amount equal to such dollar amount multiplied by the cost-of-living adjustment determined under section 1(f)(3) for such calendar year by substituting ‘1994’ for ‘1992’ in subparagraph (B) thereof. Any increase under the preceding sentence shall be rounded to the nearest multiple of \$1,000.”.

(b) EXCEPTIONS.—

(1) IN GENERAL.—Section 877 is amended by striking subsection (d), by redesignating subsection (c) as subsection (d), and by inserting after subsection (b) the following new subsection:

“(c) TAX AVOIDANCE NOT PRESUMED IN CERTAIN CASES.—

“(1) IN GENERAL.—Subsection (a)(2) shall not apply to an individual if—

“(A) such individual is described in a subparagraph of paragraph (2) of this subsection, and

“(B) within the 1-year period beginning on the date of the loss of United States citizenship, such individual submits a ruling request for the Secretary's determination as to whether such loss has for one of its principal purposes the avoidance of taxes under this subtitle or subtitle B.

“(2) INDIVIDUALS DESCRIBED.—

“(A) DUAL CITIZENSHIP, ETC.—An individual is described in this subparagraph if—

“(i) the individual became at birth a citizen of the United States and a citizen of another country and continues to be a citizen of such other country, or

“(ii) the individual becomes (not later than the close of a reasonable period after loss of United States citizenship) a citizen of the country in which—

“(I) such individual was born,

“(II) if such individual is married, such individual's spouse was born, or

“(III) either of such individual's parents were born.

“(B) LONG-TERM FOREIGN RESIDENTS.—An individual is described in this subparagraph if, for each year in the 10-year period ending on the date of loss of United States citizenship, the individual was present in the United States for 30 days or less. The rule of section 7701(b)(3)(D)(ii) shall apply for purposes of this subparagraph.

“(C) RENUNCIATION UPON REACHING AGE OF MAJORITY.—An individual is described in this subparagraph if the individual's loss of United States citizenship occurs before such individual attains age 18½.

“(D) INDIVIDUALS SPECIFIED IN REGULATIONS.—An individual is described in this subparagraph if the individual is described in a category of individuals prescribed by regulation by the Secretary.”.

(2) TECHNICAL AMENDMENT.—Paragraph (1) of section 877(b) of such Code is amended by striking “subsection (c)” and inserting “subsection (d)”.

(c) TREATMENT OF PROPERTY DISPOSED OF IN NONRECOGNITION TRANSACTIONS; TREATMENT OF DISTRIBUTIONS FROM CERTAIN CONTROLLED FOREIGN CORPORATIONS.—Subsection (d) of section 877, as redesignated by subsection (b), is amended to read as follows:

“(d) SPECIAL RULES FOR SOURCE, ETC.—For purposes of subsection (b)—

“(1) SOURCE RULES.—The following items of gross income shall be treated as income from sources within the United States:

“(A) SALE OF PROPERTY.—Gains on the sale or exchange of property (other than stock or debt obligations) located in the United States.

“(B) STOCK OR DEBT OBLIGATIONS.—Gains on the sale or exchange of stock issued by a domestic corporation or debt obligations of United States persons or of the United States, a State or political subdivision thereof, or the District of Columbia.

“(C) INCOME OR GAIN DERIVED FROM CONTROLLED FOREIGN CORPORATION.—Any income or gain derived from stock in a foreign corporation but only—

“(i) if the individual losing United States citizenship owned (within the meaning of section 958(a)), or is considered as owning (by applying the ownership rules of section 958(b)), at any time during the 2-year period ending on the date of the loss of United States citizenship, more than 50 percent of—

“(I) the total combined voting power of all classes of stock entitled to vote of such corporation, or

“(II) the total value of the stock of such corporation, and

“(ii) to the extent such income or gain does not exceed the earnings and profits attributable to such stock which were earned or accumulated before the loss of citizenship and during periods that the ownership requirements of clause (i) are met.

“(2) GAIN RECOGNITION ON CERTAIN EXCHANGES.—

“(A) IN GENERAL.—In the case of any exchange of property to which this paragraph applies, notwithstanding any other provision of this title, such property shall be treated as sold for its fair market value on the date of such exchange, and any gain shall be recognized for the taxable year which includes such date.

“(B) EXCHANGES TO WHICH PARAGRAPH APPLIES.—This paragraph shall apply to any exchange during the 10-year period described in subsection (a) if—

“(i) gain would not (but for this paragraph) be recognized on such exchange in whole or in part for purposes of this subtitle,
“(ii) income derived from such property was from sources within the United States (or, if no income was so derived, would have been from such sources), and

“(iii) income derived from the property acquired in the exchange would be from sources outside the United States.

“(C) EXCEPTION.—Subparagraph (A) shall not apply if the individual enters into an agreement with the Secretary which specifies that any income or gain derived from the property acquired in the exchange (or any other property which has a basis determined in whole or part by reference to such property) during such 10-year period shall be treated as from sources within the United States. If the property transferred in the exchange is disposed of by the person acquiring such property, such agreement shall terminate and any gain which was not recognized by reason of such agreement shall be recognized as of the date of such disposition.

“(D) SECRETARY MAY EXTEND PERIOD.—To the extent provided in regulations prescribed by the Secretary, subparagraph (B) shall be applied by substituting the 15-year period beginning 5 years before the loss of United States citizenship for the 10-year period referred to therein.

“(E) SECRETARY MAY REQUIRE RECOGNITION OF GAIN IN CERTAIN CASES.—To the extent provided in regulations prescribed by the Secretary—

“(i) the removal of appreciated tangible personal property from the United States, and

“(ii) any other occurrence which (without recognition of gain) results in a change in the source of the income or gain from property from sources within the United States to sources outside the United States,

shall be treated as an exchange to which this paragraph applies.

“(3) SUBSTANTIAL DIMINISHING OF RISKS OF OWNERSHIP.—For purposes of determining whether this section applies to any gain on the sale or exchange of any property, the running of the 10-year period described in subsection (a) shall be suspended for any period during which the individual's risk of loss with respect to the property is substantially diminished by—

“(A) the holding of a put with respect to such property (or similar property),

“(B) the holding by another person of a right to acquire the property, or

“(C) a short sale or any other transaction.

“(4) TREATMENT OF PROPERTY CONTRIBUTED TO CONTROLLED FOREIGN CORPORATIONS.—

“(A) IN GENERAL.—If—

“(i) an individual losing United States citizenship contributes property to any corporation which, at the time of the contribution, is described in subparagraph (B), and

“(ii) income derived from such property was from sources within the United States (or, if no income was so derived, would have been from such sources),

during the 10-year period referred to in subsection (a), any income or gain on such property (or any other property which has a basis determined in whole or part by reference to such property) received or accrued by the corporation shall be treated as received or accrued directly by such individual and not by such corporation. The preceding sentence shall not apply to the extent the property has been treated under subparagraph (C) as having been sold by such corporation.

“(B) CORPORATION DESCRIBED.—A corporation is described in this subparagraph with respect to an individual if, were such individual a United States citizen—

“(i) such corporation would be a controlled foreign corporation (as defined in 957), and

“(ii) such individual would be a United States shareholder (as defined in section 951(b)) with respect to such corporation.

“(C) DISPOSITION OF STOCK IN CORPORATION.—If stock in the corporation referred to in subparagraph (A) (or any other stock which has a basis determined in whole or part by reference to such stock) is disposed of during the 10-year period referred to in subsection (a) and while the property referred to in subparagraph (A) is held by such corporation, a pro rata share of such property (determined on the basis of the value of such stock) shall be treated as sold by the corporation immediately before such disposition.

“(D) ANTI-ABUSE RULES.—The Secretary shall prescribe such regulations as may be necessary to prevent the avoidance of the purposes of this paragraph, including where—

“(i) the property is sold to the corporation, and

“(ii) the property taken into account under subparagraph (A) is sold by the corporation.

“(E) INFORMATION REPORTING.—The Secretary shall require such information reporting as is necessary to carry out the purposes of this paragraph.”.

(d) CREDIT FOR FOREIGN TAXES IMPOSED ON UNITED STATES SOURCE INCOME.—

(1) Subsection (b) of section 877 is amended by adding at the end the following new sentence: “The tax imposed solely by reason of this section shall be reduced (but not below zero) by the amount of any income, war profits, and excess profits taxes (within the meaning of section 903) paid to any foreign country or possession of the United States on any income of the taxpayer on which tax is imposed solely by reason of this section.”

(2) Subsection (a) of section 877, as amended by subsection (a), is amended by inserting “(after any reduction in such tax under the last sentence of such subsection)” after “such subsection”.

(e) COMPARABLE ESTATE AND GIFT TAX TREATMENT.—

(1) ESTATE TAX.—

<< 26 USCA § 2107 >>

(A) IN GENERAL.—Subsection (a) of section 2107 is amended to read as follows:

“(a) TREATMENT OF EXPATRIATES.—

“(1) RATE OF TAX.—A tax computed in accordance with the table contained in section 2001 is hereby imposed on the transfer of the taxable estate, determined as provided in section 2106, of every decedent nonresident not a citizen of the United States if, within the 10-year period ending with the date of death, such decedent lost United States citizenship, unless such loss did not have for one of its principal purposes the avoidance of taxes under this subtitle or subtitle A.

“(2) CERTAIN INDIVIDUALS TREATED AS HAVING TAX AVOIDANCE PURPOSE.—

“(A) IN GENERAL.—For purposes of paragraph (1), an individual shall be treated as having a principal purpose to avoid such taxes if such individual is so treated under section 877(a)(2).

“(B) EXCEPTION.—Subparagraph (A) shall not apply to a decedent meeting the requirements of section 877(c)(1).”.

(B) CREDIT FOR FOREIGN DEATH TAXES.—Subsection (c) of section 2107 is amended by redesignating paragraph (2) as paragraph (3) and by inserting after paragraph (1) the following new paragraph:

“(2) CREDIT FOR FOREIGN DEATH TAXES.—

“(A) IN GENERAL.—The tax imposed by subsection (a) shall be credited with the amount of any estate, inheritance, legacy, or succession taxes actually paid to any foreign country in respect of any property which is included in the gross estate solely by reason of subsection (b).

“(B) LIMITATION ON CREDIT.—The credit allowed by subparagraph (A) for such taxes paid to a foreign country shall not exceed the lesser of—

“(i) the amount which bears the same ratio to the amount of such taxes actually paid to such foreign country in respect of property included in the gross estate as the value of the property included in the gross estate solely by reason of subsection (b) bears to the value of all property subjected to such taxes by such foreign country, or

“(ii) such property's proportionate share of the excess of—

“(I) the tax imposed by subsection (a), over

“(II) the tax which would be imposed by section 2101 but for this section.

“(C) PROPORTIONATE SHARE.—For purposes of subparagraph (B), a property's proportionate share is the percentage of the value of the property which is included in the gross estate solely by reason of subsection (b) bears to the total value of the gross estate.”.

(C) EXPANSION OF INCLUSION IN GROSS ESTATE OF STOCK OF FOREIGN CORPORATIONS.—Paragraph (2) of section 2107(b) is amended by striking “more than 50 percent of” and all that follows and inserting “more than 50 percent of—

“(A) the total combined voting power of all classes of stock entitled to vote of such corporation, or

“(B) the total value of the stock of such corporation.”.

<< 26 USCA § 2501 >>

(2) GIFT TAX.—

(A) IN GENERAL.—Paragraph (3) of section 2501(a) is amended to read as follows:

“(3) EXCEPTION.—

“(A) CERTAIN INDIVIDUALS.—Paragraph (2) shall not apply in the case of a donor who, within the 10-year period ending with the date of transfer, lost United States citizenship, unless such loss did not have for one of its principal purposes the avoidance of taxes under this subtitle or subtitle A.

“(B) CERTAIN INDIVIDUALS TREATED AS HAVING TAX AVOIDANCE PURPOSE.—For purposes of subparagraph (A), an individual shall be treated as having a principal purpose to avoid such taxes if such individual is so treated under section 877(a)(2).

“(C) EXCEPTION FOR CERTAIN INDIVIDUALS.—Subparagraph (B) shall not apply to a decedent meeting the requirements of section 877(c)(1).

“(D) CREDIT FOR FOREIGN GIFT TAXES.—The tax imposed by this section solely by reason of this paragraph shall be credited with the amount of any gift tax actually paid to any foreign country in respect of any gift which is taxable under this section solely by reason of this paragraph.”.

(f) COMPARABLE TREATMENT OF LAWFUL PERMANENT RESIDENTS WHO CEASE TO BE TAXED AS RESIDENTS.—

<< 26 USCA § 877 >>

(1) IN GENERAL.—Section 877 is amended by redesignating subsection (e) as subsection (f) and by inserting after subsection (d) the following new subsection:

“(e) COMPARABLE TREATMENT OF LAWFUL PERMANENT RESIDENTS WHO CEASE TO BE TAXED AS RESIDENTS.—

“(1) IN GENERAL.—Any long-term resident of the United States who—

“(A) ceases to be a lawful permanent resident of the United States (within the meaning of section 7701(b)(6)), or

“(B) commences to be treated as a resident of a foreign country under the provisions of a tax treaty between the United States and the foreign country and who does not waive the benefits of such treaty applicable to residents of the foreign country,

shall be treated for purposes of this section and sections 2107, 2501, and 6039F in the same manner as if such resident were a citizen of the United States who lost United States citizenship on the date of such cessation or commencement.

“(2) LONG-TERM RESIDENT.—For purposes of this subsection, the term ‘long-term resident’ means any individual (other than a citizen of the United States) who is a lawful permanent resident of the United States in at least 8 taxable years during the period of 15 taxable years ending with the taxable year during which the event described in subparagraph (A) or (B) of paragraph (1) occurs. For purposes of the preceding sentence, an individual shall not be treated as a lawful permanent resident for any taxable year if such individual is treated as a resident of a foreign country for the taxable year under the provisions of a tax treaty between the United States and the foreign country and does not waive the benefits of such treaty applicable to residents of the foreign country.

“(3) SPECIAL RULES.—

“(A) EXCEPTIONS NOT TO APPLY.—Subsection (c) shall not apply to an individual who is treated as provided in paragraph (1).

“(B) STEP-UP IN BASIS.—Solely for purposes of determining any tax imposed by reason of this subsection, property which was held by the long-term resident on the date the individual first became a resident of the United States shall be treated as having a basis on such date of not less than the fair market value of such property on such date. The preceding sentence shall not apply if the individual elects not to have such sentence apply. Such an election, once made, shall be irrevocable.

“(4) AUTHORITY TO EXEMPT INDIVIDUALS.—This subsection shall not apply to an individual who is described in a category of individuals prescribed by regulation by the Secretary.

“(5) REGULATIONS.—The Secretary shall prescribe such regulations as may be appropriate to carry out this subsection, including regulations providing for the application of this subsection in cases where an alien individual becomes a resident of the United States during the 10-year period after being treated as provided in paragraph (1).”.

(2) CONFORMING AMENDMENTS.—

<< 26 USCA § 2107 >>

(A) Section 2107 is amended by striking subsection (d), by redesignating subsection (e) as subsection (d), and by inserting after subsection (d) (as so redesignated) the following new subsection:

“(e) CROSS REFERENCE.—

“For comparable treatment of long-term lawful permanent residents who ceased to be taxed as residents, see section 877(e).”.

<< 26 USCA § 2501 >>

(B) Paragraph (3) of section 2501(a) (as amended by subsection (e)) is amended by adding at the end the following new subparagraph:

“(E) CROSS REFERENCE.—

“For comparable treatment of long-term lawful permanent residents who ceased to be taxed as residents, see section 877(e).”.

<< 26 USCA §§ 877 NOTE, 2107 nt, 2501 nt >>

(g) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to—

(A) individuals losing United States citizenship (within the meaning of section 877 of the Internal Revenue Code of 1986) on or after February 6, 1995, and

(B) long-term residents of the United States with respect to whom an event described in subparagraph (A) or (B) of section 877(e)(1) of such Code occurs on or after February 6, 1995.

(2) RULING REQUESTS.—In no event shall the 1-year period referred to in section 877(c)(1)(B) of such Code, as amended by this section, expire before the date which is 90 days after the date of the enactment of this Act.

(3) SPECIAL RULE.—

(A) IN GENERAL.—In the case of an individual who performed an act of expatriation specified in paragraph (1), (2), (3), or (4) of section 349(a) of the Immigration and Nationality Act (8 U.S.C. 1481(a)(1)–(4)) before February 6, 1995, but who did not, on or before such date, furnish to the United States Department of State a signed statement of voluntary relinquishment of United States nationality confirming the performance of such act, the amendments made by this section and section 512 shall apply to such individual except that the 10-year period described in section 877(a) of such Code shall not expire before the end of the 10-year period beginning on the date such statement is so furnished.

(B) EXCEPTION.—Subparagraph (A) shall not apply if the individual establishes to the satisfaction of the Secretary of the Treasury that such loss of United States citizenship occurred before February 6, 1994.

SEC. 512. INFORMATION ON INDIVIDUALS LOSING UNITED STATES CITIZENSHIP.

<< 26 USCA § 6039F >>

(a) IN GENERAL.—Subpart A of part III of subchapter A of chapter 61 is amended by inserting after section 6039E the following new section:

“SEC. 6039F. INFORMATION ON INDIVIDUALS LOSING UNITED STATES CITIZENSHIP.

“(a) IN GENERAL.—Notwithstanding any other provision of law, any individual who loses United States citizenship (within the meaning of section 877(a)) shall provide a statement which includes the information described in subsection (b). Such statement shall be—

“(1) provided not later than the earliest date of any act referred to in subsection (c), and

“(2) provided to the person or court referred to in subsection (c) with respect to such act.

“(b) INFORMATION TO BE PROVIDED.—Information required under subsection (a) shall include—

“(1) the taxpayer's TIN,

“(2) the mailing address of such individual's principal foreign residence,

“(3) the foreign country in which such individual is residing,

“(4) the foreign country of which such individual is a citizen,

“(5) in the case of an individual having a net worth of at least the dollar amount applicable under section 877(a)(2)(B), information detailing the assets and liabilities of such individual, and

“(6) such other information as the Secretary may prescribe.

“(c) ACTS DESCRIBED.—For purposes of this section, the acts referred to in this subsection are—

“(1) the individual's renunciation of his United States nationality before a diplomatic or consular officer of the United States pursuant to paragraph (5) of section 349(a) of the Immigration and Nationality Act (8 U.S.C. 1481(a)(5)),

“(2) the individual's furnishing to the United States Department of State a signed statement of voluntary relinquishment of United States nationality confirming the performance of an act of expatriation specified in paragraph (1), (2), (3), or (4) of section 349(a) of the Immigration and Nationality Act (8 U.S.C. 1481(a)(1)–(4)),

“(3) the issuance by the United States Department of State of a certificate of loss of nationality to the individual, or

“(4) the cancellation by a court of the United States of a naturalized citizen's certificate of naturalization.

“(d) PENALTY.—Any individual failing to provide a statement required under subsection (a) shall be subject to a penalty for each year (of the 10-year period beginning on the date of loss of United States citizenship) during any portion of which such failure continues in an amount equal to the greater of—

“(1) 5 percent of the tax required to be paid under section 877 for the taxable year ending during such year, or

“(2) \$1,000,

unless it is shown that such failure is due to reasonable cause and not to willful neglect.

“(e) INFORMATION TO BE PROVIDED TO SECRETARY.—Notwithstanding any other provision of law—

“(1) any Federal agency or court which collects (or is required to collect) the statement under subsection (a) shall provide to the Secretary—

“(A) a copy of any such statement, and

“(B) the name (and any other identifying information) of any individual refusing to comply with the provisions of subsection (a),

“(2) the Secretary of State shall provide to the Secretary a copy of each certificate as to the loss of American nationality under section 358 of the Immigration and Nationality Act which is approved by the Secretary of State, and

“(3) the Federal agency primarily responsible for administering the immigration laws shall provide to the Secretary the name of each lawful permanent resident of the United States (within the meaning of section 7701(b)(6)) whose status as such has been revoked or has been administratively or judicially determined to have been abandoned.

Notwithstanding any other provision of law, not later than 30 days after the close of each calendar quarter, the Secretary shall publish in the Federal Register the name of each individual losing United States citizenship (within the meaning of section 877(a)) with respect to whom the Secretary receives information under the preceding sentence during such quarter.

“(f) REPORTING BY LONG-TERM LAWFUL PERMANENT RESIDENTS WHO CEASE TO BE TAXED AS RESIDENTS.—In lieu of applying the last sentence of subsection (a), any individual who is required to provide a statement under this section by reason of section 877(e)(1) shall provide such statement with the return of tax imposed by chapter 1 for the taxable year during which the event described in such section occurs.

“(g) EXEMPTION.—The Secretary may by regulations exempt any class of individuals from the requirements of this section if he determines that applying this section to such individuals is not necessary to carry out the purposes of this section.”.

<< 26 USCA Ch. 61 >>

(b) CLERICAL AMENDMENT.—The table of sections for such subpart A is amended by inserting after the item relating to section 6039E the following new item:

“Sec. 6039F. Information on individuals losing United States citizenship.”.

<< 26 USCA § 6039F NOTE >>

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to—

- (1) individuals losing United States citizenship (within the meaning of section 877 of the Internal Revenue Code of 1986) on or after February 6, 1995, and
- (2) long-term residents of the United States with respect to whom an event described in subparagraph (A) or (B) of section 877(e)(1) of such Code occurs on or after such date.

In no event shall any statement required by such amendments be due before the 90th day after the date of the enactment of this Act.

SEC. 513. REPORT ON TAX COMPLIANCE BY UNITED STATES CITIZENS AND RESIDENTS LIVING ABROAD.

Not later than 90 days after the date of the enactment of this Act, the Secretary of the Treasury shall prepare and submit to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate a report—

- (1) describing the compliance with subtitle A of the Internal Revenue Code of 1986 by citizens and lawful permanent residents of the United States (within the meaning of section 7701(b)(6) of such Code) residing outside the United States, and
- (2) recommending measures to improve such compliance (including improved coordination between executive branch agencies).

Subtitle C—Repeal of Financial Institution Transition Rule to Interest Allocation Rules

<< 26 USCA § 864 NOTE >>

SEC. 521. REPEAL OF FINANCIAL INSTITUTION TRANSITION RULE TO INTEREST ALLOCATION RULES.

(a) IN GENERAL.—Paragraph (5) of section 1215(c) of the Tax Reform Act of 1986 (Public Law 99-514, 100 Stat. 2548) is hereby repealed.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendment made by this section shall apply to taxable years beginning after December 31, 1995.

(2) SPECIAL RULE.—In the case of the first taxable year beginning after December 31, 1995, the pre-effective date portion of the interest expense of the corporation referred to in such paragraph (5) of such section 1215(c) for such taxable year shall be allocated and apportioned without regard to such amendment. For purposes of the preceding sentence, the pre-effective date portion is the amount which bears the same ratio to the interest expense for such taxable year as the number of days during such taxable year before the date of the enactment of this Act bears to 366.

Approved August 21, 1996.

PL 104-191, 1996 HR 3103

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Unconstitutional or Preempted Limitation Recognized by [Krafsur v. Davenport](#), 6th Cir.(Tenn.), Dec. 04, 2013



KeyCite Yellow Flag - Negative Treatment

Proposed Legislation

United States Code Annotated

Title 5. Government Organization and Employees (Refs & Annos)

Part I. The Agencies Generally

Chapter 7. Judicial Review (Refs & Annos)

5 U.S.C.A. § 706

§ 706. Scope of review

Currentness

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

- (1) compel agency action unlawfully withheld or unreasonably delayed; and
- (2) hold unlawful and set aside agency action, findings, and conclusions found to be--
 - (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
 - (B) contrary to constitutional right, power, privilege, or immunity;
 - (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
 - (D) without observance of procedure required by law;
 - (E) unsupported by substantial evidence in a case subject to [sections 556](#) and [557](#) of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
 - (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

CREDIT(S)

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

Notes of Decisions (5815)

5 U.S.C.A. § 706, 5 USCA § 706

Current through P.L. 118-158. Some statute sections may be more current, see credits for details.

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89 FR 32976-01, 2024 WL 1801644(F.R.)
RULES and REGULATIONS
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
45 CFR Parts 160 and 164
RIN 0945-AA20

HIPAA Privacy Rule To Support Reproductive Health Care Privacy

Friday, April 26, 2024

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services.

***32976 ACTION:** Final rule.

SUMMARY: The Department of Health and Human Services (HHS or “Department”) is issuing this final rule to modify the Standards for Privacy of Individually Identifiable Health Information (“Privacy Rule”) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act). The Department is issuing this final rule after careful consideration of all public comments received in response to the notice of proposed rulemaking (NPRM) for the HIPAA Privacy Rule to Support Reproductive Health Care Privacy (“2023 Privacy Rule NPRM”) and public comments received on proposals to revise provisions of the HIPAA Privacy Rule in the NPRM for the Confidentiality of Substance Use Disorder (SUD) Patient Records (“2022 Part 2 NPRM”).

DATES:

Effective date: This final rule is effective on June 25, 2024.

Compliance date: Persons subject to this regulation must comply with the applicable requirements of this final rule by December 23, 2024, except for the applicable requirements of [45 CFR 164.520](#) in this final rule. Persons subject to this regulation must comply with the applicable requirements of [45 CFR 164.520](#) in this final rule by February 16, 2026.

FOR FURTHER INFORMATION CONTACT: Marissa Gordon-Nguyen at (202) 240-3110 or (800) 537-7697 (TDD), or by email at OCRPrivacy@hhs.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Overview

B. Effective and Compliance Dates

1. 2023 Privacy Rule NPRM

2. Overview of Comments

3. Final Rule

4. Response to Public Comments

II. Statutory and Regulatory Background

A. Statutory Authority and History

1. Health Insurance Portability and Accountability Act of 1996 (HIPAA)
2. Health Information Technology for Economic and Clinical Health (HITECH) Act

B. Regulatory History

1. 2000 Privacy Rule
2. 2002 Privacy Rule
3. 2013 Omnibus Rule
4. 2024 Privacy Rule

III. Justification for This Rulemaking

A. HIPAA Encourages Trust and Confidence by Carefully Balancing Individuals' Privacy Interests With Others' Interests in Using or Disclosing PHI

1. Privacy Protections Ensure That Individuals Have Access to, and Are Comfortable Accessing, High-Quality Health Care
2. The Department's Approach to the Privacy Rule Has Long Sought To Balance the Interests of Individuals and Society

B. Developments in the Legal Environment Are Eroding Individuals' Trust in the Health Care System

C. To Protect the Trust Between Individuals and Health Care Providers, the Department Is Restricting Certain Uses and Disclosures of PHI for Particular Non-Health Care Purposes

IV. General Discussion of Public Comments

A. General Comments in Support of the Proposed Rule

B. General Comments in Opposition to the Proposed Rule

C. Other General Comments on the Proposed Rule

V. Summary of Final Rule Provisions and Public Comments and Responses

A. Section 160.103 Definitions

1. Clarifying the Definition of “Person”
2. Interpreting Terms Used in Section 1178(b) of the Social Security Act
3. Adding a Definition of “Reproductive Health Care”
4. Whether the Department Should Define Any Additional Terms

B. Section 164.502—Uses and Disclosures of Protected Health Information: General Rules

1. Clarifying When PHI May Be Used or Disclosed by Regulated Entities

2. Adding a New Category of Prohibited Uses and Disclosures
3. Clarifying Personal Representative Status in the Context of Reproductive Health Care
4. Request for Comments
- C. Section 164.509—Uses and Disclosures for Which an Attestation is Required
 1. Current Provision
 2. Proposed Rule
 3. Overview of Public Comments
 4. Final Rule
 5. Responses to Public Comments
- D. Section 164.512—Uses and Disclosures for Which an Authorization or Opportunity To Agree or Object Is Not Required
 1. Applying the Prohibition and Attestation Condition to Certain Permitted Uses and Disclosures
 2. Making a Technical Correction to the Heading of [45 CFR 164.512\(c\)](#) and Clarifying That Providing or Facilitating Reproductive Health Care Is Not Abuse, Neglect, or Domestic Violence
 3. Clarifying the Permission for Disclosures Based on Administrative Processes
 4. Request for Information on Current Processes for Receiving and Addressing Requests Pursuant to 164.512(d) Through (g)(1)
- E. [Section 164.520](#)—Notice of Privacy Practices for Protected Health Information
 1. Current Provision
 2. CARES Act
 3. Proposals in 2022 Part 2 NPRM and 2023 Privacy Rule NPRM
 4. Overview of Public Comments
 5. Final Rule
 6. Responses to Public Comments
- F. Section 164.535—Severability
- G. Comments on Other Provisions of the HIPAA Rules
- VI. Regulatory Impact Analysis
 - A. [Executive Order 12866](#) and Related Executive Orders on Regulatory Review
 1. Summary of Costs and Benefits
 2. Baseline Conditions
 3. Costs of the Rule

B. Regulatory Alternatives to the Final Rule

C. Regulatory Flexibility Act—Small Entity Analysis

D. [Executive Order 13132](#)—Federalism

E. Assessment of Federal Regulation and Policies on Families

F. Paperwork Reduction Act of 1995

Explanation of Estimated Annualized Burden Hours

Table of Acronyms

Term	Meaning
Part V	
AMA	American Medical Association.
API	Application Programming Interface.
CARES Act	Coronavirus Aid, Relief, and Economic Security Act.
CDC	Centers for Disease Control and Prevention.
CLIA	Clinical Laboratory Improvement Amendments of 1988.
CMS	Centers for Medicare & Medicaid Services.
DOD	Department of Defense.
Department or HHS	Department of Health and Human Services.
EHR	Electronic Health Record.
E.O.	Executive Order.
FDA	Food and Drug Administration.
FHIR®	Fast Healthcare Interoperability Resources®.
FTC	Federal Trade Commission.
GINA	Genetic Information Nondiscrimination Act of 2008.
Health IT	Health Information Technology.
HIE	Health Information Exchange.
HIPAA	Health Insurance Portability and Accountability Act of 1996.
HITECH Act	Health Information Technology for Economic and Clinical Health Act of 2009.
ICR	Information Collection Request.

IIHI	Individually Identifiable Health Information.
NCVHS	National Committee on Vital and Health Statistics.
NICS	National Instant Criminal Background Check System.
NPP	Notice of Privacy Practices.
NPRM	Notice of Proposed Rulemaking.
OCR	Office for Civil Rights.
OHCA	Organized Health Care Arrangement.
OMB	Office of Management and Budget.
ONC	Office of the National Coordinator for Health Information Technology.
PHI	Protected Health Information.
PRA	Paperwork Reduction Act of 1995.
RFA	Regulatory Flexibility Act.
RIA	Regulatory Impact Analysis.
SBA	Small Business Administration.
SSA	Social Security Act of 1935.
TPO	Treatment, Payment, or Health Care Operations.
UMRA	Unfunded Mandates Reform Act of 1995.

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I. Executive Summary

A. Overview

In this final rule, the Department of Health and Human Services (HHS or “Department”) modifies certain provisions of the Standards for Privacy of Individually Identifiable Health Information (“Privacy Rule”), issued pursuant to section 264 of the Administrative Simplification provisions of title II, subtitle F, of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[FN1] The Privacy Rule [FN2] is one of several rules, collectively known as the HIPAA Rules,[FN3] that protect the privacy and security of individuals' protected health information [FN4] (PHI), which is individually identifiable health information [FN5] (IIHI) transmitted by or maintained in electronic media or any other form or medium, with certain exceptions.[FN6]

The Privacy Rule requires the disclosure of PHI only in the following circumstances: when required by the Secretary to investigate a regulated entity's compliance with the Privacy Rule and to the individual pursuant to the individual's right of access and the individual's right to an accounting of disclosures.[FN7] Any other uses or disclosures described in the Privacy Rule are either permitted or prohibited, as specified in the Privacy Rule. For example, the Privacy Rule permits, but does not require, a regulated entity to disclose PHI to conduct quality improvement activities when applicable conditions are met, and it prohibits a regulated entity from selling PHI except pursuant to and in compliance with 45 CFR 164.508(a)(4).[FN8]

In accordance with its statutory mandate, the Department promulgated the Privacy Rule and continues to administer and enforce it to ensure that individuals are not afraid to seek health care from, or share important information with, their health care providers because of a concern that their sensitive information will be disclosed outside of their relationship with their health care provider. Protecting privacy promotes trust between health care providers and individuals, advancing access to and improving the quality of health care. To achieve this goal, the Department generally has applied the same privacy standards to nearly all PHI, regardless of the type of health care at issue. Notably, special protections were given to psychotherapy notes, owing in part to the particularly ***32978** sensitive information those notes contain.[FN9]

Under its statutory authority to administer and enforce the HIPAA Rules, the Department may modify the HIPAA Rules as needed.[FN10] The Supreme Court decision in *Dobbs v. Jackson Women's Health Organization* [FN11] (*Dobbs*) overturned precedent that protected a constitutional right to abortion and altered the legal and health care landscape. This decision has far-reaching implications for reproductive health care beyond its effects on access to abortion.[FN12] This changing legal landscape increases the likelihood that an individual's PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect, including the trust of individuals in health care providers and the health care system.[FN13] The threat that PHI will be disclosed and used to conduct such an investigation against, or to impose liability upon, an individual or another person is likely to chill an individual's willingness to seek lawful health care treatment or to provide full information to their health care providers when obtaining that treatment, and on the willingness of health care providers to provide such care.[FN14] These developments in the legal environment increase the potential that use and disclosure of PHI about an individual's reproductive health will undermine access to and the quality of health care generally.

In order to continue to protect privacy in a manner that promotes trust between individuals and health care providers and advances access to, and improves the quality of, health care, we have determined that the Privacy Rule must be modified to limit the circumstances in which provisions of the Privacy Rule permit the use or disclosure of an individual's PHI about reproductive health care for certain non-health care purposes, where such use or disclosure could be detrimental to privacy of the individual or another person or the individual's trust in their health care providers. This determination was informed by our expertise in administering the Privacy Rule, questions we have received from members of the public and Congress, comments we received on the 2023 HIPAA Privacy Rule to Support Reproductive Health Care Privacy notice of proposed rulemaking (NPRM) ("2023 Privacy Rule NPRM"),[FN15] and our analysis of the state of privacy for IIHI.

This final rule ("2024 Privacy Rule") amends provisions of the Privacy Rule to strengthen privacy protections for highly sensitive PHI about the reproductive health care of an individual, and directly advances the purposes of HIPAA by setting minimum protections for PHI and providing peace of mind that is essential to individuals' ability to obtain lawful reproductive health care. This final rule balances the interests of society in obtaining PHI for non-health care purposes with the interests of the individual, the Federal Government, and society in protecting individual privacy, thereby improving the effectiveness of the health care system by ensuring that persons are not deterred from seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided.

The Department carefully analyzed state prohibitions and restrictions on an individual's ability to obtain high-quality health care and their effects on health information privacy and the relationships between individuals and their health care providers after *Dobbs*; assessed trends in state legislative activity with respect to the privacy of PHI; and conducted a thorough review of the text, history, and purposes of HIPAA and the Privacy Rule. The Department also engaged in extensive discussions with HHS agencies and other Federal departments, including the Department of Justice; consulted with the National Committee on Vital and Health Statistics (NCVHS) and the Attorney General as required by section 264(d) of HIPAA, and with Indian Tribes as required by [Executive Order 13175](#); [FN16] held listening sessions with and reviewed correspondence from stakeholders, including covered entities, states, individuals, and patient advocates; and reviewed correspondence to HHS from Members of Congress.[FN17] The modifications made to the Privacy Rule by this final rule are the result of this work.

B. Effective and Compliance Dates

1. 2023 Privacy Rule NPRM

In the 2023 Privacy Rule NPRM, the Department proposed an effective date for a final rule that would occur 60 days after publication, and a compliance date that would occur 180 days after the effective date.[FN18] Taken together, the two dates would give entities 240 days after publication to implement compliance measures. In the preamble to the proposed rule, the Department stated that it did not believe that the proposed rule would pose unique implementation challenges that would justify an extended compliance period (i.e., a period longer than the standard 180 days provided in [45 CFR 160.105](#)).[FN19] The Department also asserted that adherence to the standard compliance period is necessary to timely address the circumstances described in the 2023 Privacy Rule NPRM.

2. Overview of Comments

A commenter urged the Department to move quickly to issue the final rule and to provide a 180-day compliance period *32979 as proposed. Some commenters requested that the Department provide additional time for regulated entities to comply with the proposed modifications to the Privacy Rule. Several commenters requested that the Department coordinate compliance deadlines across its rulemakings, while a few commenters specifically encouraged the Department to provide additional time for compliance with the modifications to the Notice of Privacy Practices (NPP) requirements proposed in the 2023 Privacy Rule NPRM.

3. Final Rule

This final rule is effective on June 25, 2024. Covered entities and business associates of all sizes will have 180 days beyond the effective date of the final rule to comply with the final rule's provisions, with the exception of the NPP provisions, which we address separately below. We understand that some covered entities and business associates remain concerned that a 180-day period may not provide sufficient time to come into compliance with the modified requirements. However, we believe that providing a 180-day compliance period best comports with section 1175(b)(2) of the Social Security Act of 1935 (SSA), [42 U.S.C. 1320d-4](#), and our implementing provision at [45 CFR 160.104\(c\)\(1\)](#), which require the Secretary to provide at least a 180-day period for covered entities to comply with modifications to standards and implementation specifications in the HIPAA Rules, and also that providing a 180-day compliance period best protects the privacy and security of individuals' PHI in a timely manner that reflects the urgency of addressing the changes in the legal landscape and their effects on individuals, regulated entities, and other persons, while balancing the burden imposed upon regulated entities of implementing this final rule.

[Section 160.104\(a\)](#) permits the Department to adopt a modification to a standard or implementation specification adopted under the Privacy Rule no more frequently than once every 12 months.[FN20] As discussed above, we are required to provide a minimum of a 180-day compliance period when adopting a modification, but we are permitted to provide a longer compliance period based on the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.[FN21] The Department makes every effort to consider the burden and cost of implementation for regulated entities when determining an appropriate compliance date.

While we recognize that regulated entities will need to revise and implement changes to their policies and procedures in response to the modifications in this final rule, we do not believe that these changes are so significant as to require more than a 180-day compliance period. This final rule narrowly tailors the application of its changes to certain limited circumstances involving lawful reproductive health care and clarifies that regulated entities are not expected to know or be aware of laws other than those with which they are required to comply. While it adds a condition to certain requests for uses and disclosures, the affected requests already require careful review by regulated entities for compliance with previously imposed conditions. Thus, we do not believe it will be difficult for regulated entities to adjust their policies and procedures to accommodate this new requirement. The other modifications finalized in this rule are in service of implementing the two changes above and impose minimal burden on regulated entities. Additionally, the Department believes, based on its evaluation of the evolving privacy landscape, that the changes made by this final rule are of particular urgency. Accordingly, we believe that a 180-day compliance period, combined

with a 60-day effective date, is sufficient for regulated entities to make the changes required by most of the modifications in this final rule, with the exception of the NPP provisions.

We separately consider the question of the compliance date for the modifications to the NPP provisions. In the 2022 Confidentiality of Substance Use Disorder (SUD) Patient Records NPRM (“2022 Part 2 NPRM”),[FN22] the Department proposed, among other things, to revise 45 CFR 164.520 as required by section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act.[FN23] The Department proposed to provide the same compliance date for both the proposed modifications to 45 CFR 164.520 and the more extensive modifications to 42 CFR part 2 (“Part 2”).[FN24] The 2024 Confidentiality of Substance Use Disorder (SUD) Patient Records Final Rule (“2024 Part 2 Rule”) explicitly noted that the Department was not finalizing the proposed modifications to the NPP provisions at that time, but that we planned to do so in a future HIPAA final rule.[FN25] The Department also acknowledged that some covered entities might have NPPs that would not reflect updated changes to policies and procedures addressing how Part 2 records are used and disclosed. Rather than requiring covered entities to revise their NPPs twice in a short period of time, the Department announced in the 2024 Part 2 Rule that it would exercise enforcement discretion related to the requirement that covered entities update their NPPs whenever material changes are made to privacy practices until the compliance date established by a future HIPAA final rule.[FN26] The Department is finalizing the modifications to the NPP required by section 3221 of the CARES Act in this rule and aligning the effective and compliance dates for all of the modified NPP requirements with those of the 2024 Part 2 Rule.

The compliance date of the 2024 Part 2 Rule is February 16, 2026, substantially later than the compliance date for most of this final rule, because of the significant changes required for compliance with the 2024 Part 2 Rule. Accordingly, in compliance with 45 CFR 160.104 and consistent with the NPP proposals included in the 2022 Part 2 NPRM and public comment, we are aligning the compliance date for the NPP changes required by this final rule with the compliance date for the 2024 Part 2 Rule so that covered entities regulated under both rules can implement all changes to their NPPs at the same time. Covered entities are expected to be in compliance with the modifications to 45 CFR 164.520 on February 16, 2026.

4. Response to Public Comments

Comment: One commenter expressed support for the proposal in the 2023 Privacy Rule NPRM to establish a 180-day compliance date and urged the Department to issue a final rule quickly. Some commenters sought an extension of the compliance date for twelve to eighteen months, explaining that extensive policy and legal work, process and software changes, documentation and training would be required to implement the 2023 Privacy Rule NPRM.

One commenter suggested phasing in the attestation requirement so that “downstream” regulated entities, such as business associates and managed care organizations, would have a later compliance date than health care providers.

***32980** Response: We appreciate the commenters' suggestions, but as discussed above, based on our assessment, we do not believe the modifications required by this final rule will require longer to implement.

Comment: Some commenters requested that the Department coordinate compliance deadlines of final rules that revise the Privacy Rule or publish one final rule addressing the proposals in the NPRMs to enable regulated entities to leverage the resources required to implement the changes to achieve compliance with all of the new requirements at one time.

One commenter explained that each NPRM would involve operational changes requiring significant resources and effort and expressed their belief that a single comprehensive final rule would allow regulated entities to make all of the required changes, including revisions to policies and procedures, development of new or revised workflows, electronic health record (EHR) updates, and technology enhancements.

Response: We appreciate the commenters' suggestion, but we do not believe that it is necessary to fully align the compliance dates for the 2024 Part 2 Rule and the 2024 Privacy Rule. By imposing separate compliance deadlines, we are able to act more quickly to protect the privacy of PHI.

However, consistent with 45 CFR 160.104 and as requested by public comment, we are applying the same compliance date for covered entities to revise their NPPs to address modifications made to 45 CFR 164.520 in response to and consistent with the CARES Act and to support reproductive health care privacy. The compliance date for the NPP provisions is February 16, 2026. [FN27] Part 2 programs, including those that are covered entities, can choose to implement the changes to their NPPs that are required by the 2024 Part 2 Rule prior to the compliance date, but there is no requirement that they do so.

II. Statutory and Regulatory Background

A. Statutory Authority and History

1. Health Insurance Portability and Accountability Act of 1996 (HIPAA)

In 1996, Congress enacted HIPAA [FN28] to reform the health care delivery system to “improve portability and continuity of health insurance coverage in the group and individual markets.” [FN29] To enable health care delivery system reform, Congress included in HIPAA requirements for standards to support the electronic exchange of health information. According to section 261, “[i]t is the purpose of this subtitle to improve [. . .] the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information [. . .].” [FN30] Congress applied the Administrative Simplification provisions directly to three types of entities known as “covered entities”—health plans, health care clearinghouses, and health care providers who transmit information electronically in connection with a transaction for which HHS has adopted a standard.[FN31]

Section 262(a) of HIPAA required the Secretary to adopt uniform standards “to enable health information to be exchanged electronically.” [FN32] Congress directed the Secretary to adopt standards for unique identifiers to identify individuals, employers, health plans, and health care providers across the nation [FN33] and standards for, among other things, transactions and data elements relating to health information,[FN34] the security of that information,[FN35] and verification of electronic signatures.[FN36]

Congress recognized that the standardization of certain electronic health care transactions required by HIPAA posed risks to the privacy of confidential health information and viewed individual privacy, confidentiality, and data security as critical for orderly administrative simplification.[FN37] Thus, as explained in the preamble to the 2023 Privacy Rule NPRM,[FN38] Congress provided the Department with the authority to regulate the privacy of IIHI. According to one Member of Congress, privacy standards would create an additional layer of protection beyond the oath pledged by health care providers to keep information secure and, as described by another Member, would further protect information from being used in a “malicious or discriminatory manner.” [FN39] Congress intended for the law to enhance individuals' trust in health care providers, which required that the law provide additional protection for the confidentiality of IIHI. As described by a Member of Congress: “The bill would also establish strict security standards for health information because Americans clearly want to make sure that their health care records can only be used by the medical professionals that treat them. Often, we assume that because doctors take an oath of confidentiality that in fact all who touch their records operate by the same standards. Clearly, they do not.” [FN40] Moreover, Congress considered that health care reform required an approach that would not compromise privacy as health information became more accessible.[FN41]

Accordingly, section 264(a) directed the Secretary to submit to Congress detailed recommendations for Federal “standards with respect to the privacy of [IIHI]” nationwide within one year of HIPAA's enactment.[FN42] The statute made clear that the Secretary had the authority to promulgate regulations if Congress did not enact legislation covering these matters within three years.[FN43] Congress directed the Secretary to ensure that the regulations promulgated “address at least” the following three subjects: (1) the rights that an individual who is a subject of IIHI should have; (2) the procedures that should be established for the exercise of such rights; and (3) the uses and disclosures of such information that should be authorized or required.[FN44]

Additionally, Congress provided a clear statement that HIPAA's provisions would “supersede any contrary *32981 provision of State law,” with certain limited exceptions.[FN45] One exception to this general preemption authority is for “state privacy laws that are contrary to and more stringent than the corresponding federal standard, requirement, or implementation specification.” [FN46] Thus, Congress intended for the Department to create privacy standards to safeguard health information while respecting the ability of states to provide individuals with additional health information privacy.

Congress required the Secretary to consult with the NCVHS,[FN47] thereby ensuring that the Secretary's decisions reflected public and expert involvement and advice in carrying out the requirements of section 264.[FN48] NCVHS sent its initial recommendations to the Secretary in a letter to the Secretary on June 27, 1997. Importantly, NCVHS advised that “strong substantive and procedural protections” should be imposed if health information were to be disclosed to law enforcement, and, where identifiable health information would be made available for non-health purposes, individuals should be afforded assurances that their data would not be used against them.[FN49] Additionally, NCVHS “unanimously” recommended that “[. . .] the Secretary and the Administration assign the highest priority to the development of a strong position on health privacy that provides the highest possible level of protection for the privacy rights of patients.” [FN50] NCVHS further noted that failure to do so would “undermine public confidence in the health care system, expose patients to continuing invasions of privacy, subject record keepers to potentially significant legal liability, and interfere with the ability of health care providers and others to operate the health care delivery and payment system in an effective and efficient manner,” which would undermine what Congress intended.[FN51]

NCVHS further recommended that “any rules regulating disclosures of identifiable health information be as clear and as narrow as possible. Each group of users must be required to justify their need for health information and must accept reasonable substantive and procedural limitations on access.” [FN52] According to NCVHS, this would allow for the disclosures that society deemed necessary and appropriate while providing individuals with clear expectations regarding their health information privacy.

As we noted in the 2023 Privacy Rule NPRM,[FN53] Congress contemplated that the Department's rulemaking authorities under HIPAA would not be static. Congress specifically built in a mechanism to adapt such regulations as technology and health care evolve, directing that the Secretary review and modify the Administrative Simplification standards as determined appropriate, but not more frequently than once every 12 months.[FN54] That statutory directive complements the Secretary's general rulemaking authority to “make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which each is charged under this chapter.” [FN55]

2. Health Information Technology for Economic and Clinical Health (HITECH) Act

On February 17, 2009, Congress enacted the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act) [FN56] to promote the widespread adoption and standardization of health information technology (health IT). The HITECH Act included additional HIPAA privacy and security requirements for covered entities and business associates and expanded certain rights of individuals with respect to their PHI.

Congress understood the importance of a relationship between a connected health IT landscape, “a necessary and vital component of health care reform,” [FN57] and privacy and security standards when it enacted the HITECH Act. The Purpose statement of an accompanying House of Representatives report [FN58] on the Energy and Commerce Recovery and Reinvestment Act [FN59] recognizes that “[i]n addition to costs, concerns about the security and privacy of health information have also been regarded as an obstacle to the adoption of [health IT].” The Senate Report for S. 336 [FN60] similarly acknowledges that “[i]nformation technology systems linked securely and with strong privacy protections can improve the quality and efficiency of health care while producing significant cost savings.” [FN61] As the Department explained in the 2013 regulation referred to as the “Omnibus Rule” [FN62] and discussed in greater detail below, the HITECH Act's additional HIPAA privacy and security requirements [FN63] supported Congress' goal of promoting widespread adoption and interoperability of health IT by “strengthen[ing] the privacy and security protections for health information established by HIPAA.” [FN64]

In passing the HITECH Act, Congress instructed the Department that any new health IT standards adopted under section 3004 of the Public Health Service Act (PHSA) must take into account the privacy and security requirements of the HIPAA Rules. [FN65] Congress also affirmed that the existing HIPAA Rules were to remain in effect to the extent that they are consistent with the HITECH Act and directed the Secretary to revise the HIPAA Rules as necessary for consistency with the *32982 HITECH Act.[FN66] Congress confirmed that the new law was not intended to have any effect on authorities already granted under HIPAA to the Department, including section 264 of that statute and the regulations issued under that provision.[FN67] Congress thus affirmed the Secretary's ongoing rulemaking authority to modify the Privacy Rule's standards and implementation specifications as often as every 12 months when appropriate, including to strengthen privacy and security protections for IIHI.

B. Regulatory History

The Secretary has delegated the authority to administer the HIPAA Rules and to make decisions regarding their implementation, interpretation, and enforcement to the HHS Office for Civil Rights (OCR).[FN68] Since the enactment of the HITECH Act, the Department has exercised its authority to modify the Privacy Rule several times—in 2013, 2014, and 2016.[FN69]

1. 2000 Privacy Rule

As directed by HIPAA, the Department provided a series of recommendations to Congress for a potential new law that would address the confidentiality of IIHI.[FN70] Congress did not act within its three-year self-imposed deadline. Accordingly, the Department published a proposed rule on November 3, 1999,[FN71] and issued the first final rule establishing “Standards for Privacy of Individually Identifiable Health Information” (“2000 Privacy Rule”) on December 28, 2000.[FN72]

The primary goal of the Privacy Rule was to provide greater protection to individuals' privacy to engender a trusting relationship between individuals and health care providers. As announced, the final rule set standards to protect the privacy of IIHI to “begin to address growing public concerns that advances in electronic technology and evolution in the health care industry are resulting, or may result, in a substantial erosion of the privacy surrounding” health information.[FN73] On the eve of that rule's issuance, the President issued an Executive Order recognizing the importance of protecting individual privacy, explaining that “[p]rotecting the privacy of patients' protected health information promotes trust in the health care system. It improves the quality of health care by fostering an environment in which patients can feel more comfortable in providing health care professionals with accurate and detailed information about their personal health.” [FN74]

Since its promulgation, the Privacy Rule has protected PHI by limiting the circumstances under which covered entities and their business associates (collectively, “regulated entities”) are permitted or required to use or disclose PHI and by requiring covered entities to have safeguards in place to protect the privacy of PHI. In adopting these regulations, the Department acknowledged the need to balance several competing factors, including existing legal expectations, individuals' privacy expectations, and societal expectations.[FN75] The Department noted in the preamble that the large number of comments from individuals and groups representing individuals demonstrated the deep public concern about the need to protect the privacy of IIHI and constituted evidence of the importance of protecting privacy and the potential adverse consequences to individuals and their health if such protections are not extended.[FN76] Through its policy choices in the 2000 Privacy Rule, the Department struck a balance between competing interests—the necessity of protecting privacy and the public interest in using identifiable health information for vital public and private purposes—in a way that was also workable for the varied stakeholders.[FN77]

In the 2000 Privacy Rule, the Department established “general rules” for uses and disclosures of PHI, codified at [45 CFR 164.502](#). [FN78] The 2000 Privacy Rule also specified the circumstances in which a covered entity was required to obtain an individual's consent,[FN79] authorization,[FN80] or the opportunity for the individual to agree or object.[FN81] Additionally, it established rules for when a covered entity is permitted to use or disclose PHI without an individual's consent, authorization, or opportunity to agree or object.[FN82] In particular, the Privacy Rule permits certain uses and disclosures of PHI, without the individual's authorization, for identified activities that benefit the community, such as public health activities, judicial and administrative proceedings, law enforcement purposes, and research.[FN83]

The Privacy Rule also established the rights of individuals with respect to their PHI, including the right to receive adequate notice of a covered entity's privacy practices, the right to request restrictions of uses and disclosures, the right to access (i.e., to inspect and obtain a copy of) their PHI, the right to request an amendment of their PHI, and the right to receive an accounting of disclosures.[FN84]

In the 2000 Privacy Rule, the Secretary exercised her statutory authority to adopt [45 CFR 160.104\(a\)](#), which reserves the Secretary's ability to modify any standard or implementation specification adopted under the Administrative Simplification provisions.[FN85] The Secretary first invoked this modification authority to amend the Privacy Rule in 2002 [FN86] and made additional modifications in 2013,[FN87] and 2016,[FN88] as described below.

2. 2002 Privacy Rule

After publication of the 2000 Privacy Rule, the Department received many inquiries and unsolicited comments about the Privacy Rule's effects and operation. As a result, the Department opened the 2000 Privacy Rule for further comment in February 2001, less than one month before the effective date and 25 months before the compliance date for most covered entities, and issued clarifying guidance on its implementation.[FN89] NCVHS' Subcommittee on Privacy, Confidentiality and Security held public ***32983** hearings about the 2000 Privacy Rule. From those hearings, the Department obtained additional information about concerns related to key provisions and their potential unintended consequences for health care quality and access.[FN90] On March 27, 2002, the Department proposed modifications to the 2000 Privacy Rule to clarify the requirements and correct potential problems that could threaten access to, or quality of, health care.[FN91]

In response to comments on the proposed rule, the Department finalized modifications to the Privacy Rule on August 14, 2002 ("2002 Privacy Rule").[FN92] This final rule clarified HIPAA's requirements while maintaining strong protections for the privacy of IIHI.[FN93] These modifications addressed certain workability issues, including but not limited to clarifying distinctions between health care operations and marketing; modifying the minimum necessary standard to exclude disclosures authorized by individuals and clarify its operation; eliminating the consent requirement for uses and disclosures of PHI for treatment, payment, or health care operations (TPO), and to otherwise clarify the role of consent in the Privacy Rule; and making other modifications and conforming amendments consistent with the proposed rule. The Department also included modifications to the provisions permitting the use or disclosure of PHI for public health activities and for research activities without consent, authorization, or an opportunity to agree or object.

3. 2013 Omnibus Rule

Following the enactment of the HITECH Act, the Department issued an NPRM, entitled "Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health [HITECH] Act" ("2010 NPRM"),[FN94] which proposed to implement certain HITECH Act requirements. In 2013, the Department issued the final rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health [HITECH] Act and the Genetic Information Nondiscrimination Act, and Other Modifications to the HIPAA Rules ("2013 Omnibus Rule"),[FN95] which implemented many of the new HITECH Act requirements, including strengthening individuals' privacy rights related to their PHI.

The Department also finalized regulatory provisions that were not required by the HITECH Act, but were necessary to address the workability and effectiveness of the Privacy Rule and to increase flexibility for and decrease burden on regulated entities.[FN96] In the 2010 NPRM, the Department noted that it had not amended the Privacy Rule since 2002.[FN97] It further explained that information gleaned from contact with the public since that time, enforcement experience, and technical corrections needed to eliminate ambiguity provided the impetus for the Department's actions to make certain regulatory changes. [FN98]

For example, the Department modified its prior interpretation of the Privacy Rule requirement at [45 CFR 164.508\(c\)\(1\)\(iv\)](#) that a description of a research purpose must be study specific.[FN99] The Department explained that, under its new interpretation,

the research purposes need only be described adequately such that it would be reasonable for an individual to expect that their PHI could be used or disclosed for such future research.[FN100] In the 2013 Omnibus Rule, the Department explained that this change was based on the concerns expressed by covered entities, researchers, and other commenters on the 2010 NPRM that the former requirement did not represent current research practices. The Department provided a similar explanation for its modifications to the Privacy Rule that permit certain disclosures of student immunization records to schools without an authorization.[FN101] Additionally, based on a recommendation made at an NCVHS meeting, the Department requested comment on and finalized proposed revisions to the definition of PHI to exclude information regarding an individual who has been deceased for more than 50 years.[FN102] For the latter, the Department noted that it was balancing the privacy interests of decedents' living relatives and other affected individuals against the legitimate needs of public archivists to obtain records. [FN103]

None of the changes described in the paragraph above were required by the HITECH Act. Rather, the Department determined that it was necessary to promulgate these changes pursuant to its existing general rulemaking authority under HIPAA. NCVHS and the public also recommended other changes between the publication of the 2002 Privacy Rule and the 2013 Omnibus Rule, including the creation of specific categories of PHI, such as "Sexuality and Reproductive Health Information" that would allow for special protections of such PHI.[FN104] The Department declined to propose specific protections for certain categories of PHI at that time because of concerns about the ability of regulated entities to segment PHI and the effects on care coordination. Many of those concerns are still present and so, the Department did not propose and determined not to establish a specific category of particularly sensitive PHI in this rulemaking. Instead, as discussed more fully below, the Department is finalizing a purpose-based prohibition against certain uses and disclosures.

***32984 4. 2024 Privacy Rule**

On April 17, 2023, the Department issued an NPRM [FN105] to modify the Privacy Rule for the purpose of prohibiting uses and disclosures of PHI for criminal, civil, or administrative investigations or proceedings against persons for seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided. To properly execute the HIPAA statutory mandate, and in accordance with the regulatory authority granted to it by Congress, the Department continually monitors and evaluates the evolving environment for health information privacy nationally, including the interaction of the Privacy Rule and state statutes and regulations governing the privacy of health information. In keeping with the Department's practice, this final rule accommodates state autonomy to the extent consistent with the need to maintain rules for health information privacy that serve HIPAA's objectives. The regulation thus preempts state law only to the extent necessary to achieve Congress' directive to establish a standard for the privacy of IIHI for the purpose of improving the effectiveness of the health care system. As discussed below, achieving that objective requires individuals to trust that their health care providers will maintain privacy of PHI about lawful reproductive health care. In addition, NCVHS held a virtual public meeting that included a discussion about the proposed rule on June 14, 2023,[FN106] and provided recommendations to the Department based on this discussion, briefings at their July 2022 [FN107] and December 2022 [FN108] meetings, and the expertise of its members. [FN109] The resultant public record and subsequent recommendations submitted to the Department by NCVHS, along with other public comments on the 2023 Privacy Rule NPRM, informed the development of these modifications.

III. Justification for This Rulemaking

A. HIPAA Encourages Trust and Confidence by Carefully Balancing Individuals' Privacy Interests With Others' Interests in Using or Disclosing PHI

1. Privacy Protections Ensure That Individuals Have Access to, and Are Comfortable Accessing, High-Quality Health Care

The goal of a functioning health care system is to provide high-quality health care that results in the best possible outcomes for individuals. To achieve that goal, a functioning health care system depends in part on individuals trusting health care providers. Thus, trust between individuals and health care providers is essential to an individual's health and well-being.[FN110] Protecting

the privacy of an individual's health information is “a crucial element for honest health discussions.” [FN111] The original Hippocratic Oath required physicians to pledge to maintain the confidentiality of health information they learn about individuals. [FN112] Without confidence that private information will remain private, individuals—to their own detriment—are reluctant to share information with health care providers.

When proposing the 2000 Privacy Rule, the Department recognized that individuals may be deterred from seeking needed health care if they do not trust that their sensitive information will be kept private.[FN113] The Department described its policy choices as stemming from a motivation to develop and maintain a relationship of trust between individuals and health care providers. The Department explained that a fundamental assumption of the 2000 Privacy Rule was that the greatest benefits of improved privacy protection would be realized in the future as individuals gain increasing trust in their health care provider's ability to maintain the confidentiality of their health information.[FN114] As a result, the Privacy Rule strengthened protections for health information privacy, including the right of individuals to determine who has access to their health information.

Despite the Privacy Rule's rights and protections, individuals do not have confidence that their IHI is being protected adequately. In a 2022 survey on patient privacy, the American Medical Association (AMA) found that, of 1,000 patients surveyed: (1) nearly 75% were concerned about protecting the privacy of their own health information; and (2) 59% of patients worried about health data being used by companies to discriminate against them or their loved ones.[FN115] According to the AMA, a lack of health information privacy raises many questions about circumstances that could put individuals and health care providers in legal peril, and that the “primary purpose of increasing [health information] privacy is to build public trust, not inhibit data exchange.” [FN116]

The Federal Government also has a strong interest in ensuring that individuals have access to high-quality health care.[FN117] This is true at both an ***32985** individual and population level. In the 2000 Privacy Rule, the Department noted that high-quality health care depends on an individual being able to share sensitive information with their health care provider based on the trust that the information shared will be protected and kept confidential.[FN118] An effective health care system requires an individual to share sensitive health information with their health care providers. They do so with the reasonable expectation that this information is going to be used to treat them. The prospect of the disclosure of highly sensitive PHI by regulated entities can result in medical mistrust and the deterioration of the confidential, safe environment that is necessary to provide high-quality health care, operate a functional health care system, and improve the public's health generally.[FN119] High-quality health care cannot be attained without patient candor. Health care providers rely on an individual's health information to diagnose them and provide them with appropriate treatment options and may not be able to reach an accurate diagnosis or recommend the best course of action for the individual if the individual's medical records lack complete information about their health history. However, an individual may be unwilling to seek treatment or share highly sensitive PHI when they are concerned about the confidentiality and security of PHI provided to treating health care providers.[FN120] The Department has long recognized that health care professionals who lose the trust of their patients cannot deliver high-quality care.[FN121] Similarly, if a health care provider does not trust that the PHI they include in an individual's medical records will be kept private, the health care provider may leave gaps or include inaccuracies when preparing medical records, creating a risk that ongoing or future health care would be compromised. In contrast, heightened confidentiality and privacy protections enable a health care provider to feel confident maintaining full and complete medical records.

Incomplete medical records and health care avoidance not only inhibit the quality of health care an individual receives; they are also detrimental to efforts to improve public health. The objective of public health is to prevent disease in and improve the health of populations. Barriers that undermine the willingness of individuals to seek health care in a timely manner or to provide complete and accurate health information to their health care providers undermine the overall objective of public health. For example, individuals who are not candid with their health care providers because of concerns about potential negative consequences of a loss of privacy may withhold information about a variety of health matters that have public health implications, such as communicable diseases or vaccinations.[FN122] Experience also shows that medical mistrust—especially in communities of color and other communities that have been marginalized or negatively affected by historical and current

health care disparities—can create damaging and chilling effects on individuals' willingness to seek appropriate and lawful health care for medical conditions that can worsen without treatment.[FN123]

2. The Department's Approach to the Privacy Rule Has Long Sought To Balance the Interests of Individuals and Society

While recognizing the importance of preserving individuals' trust, the Department has consistently taken the approach of balancing the interests of the individual in the privacy of their PHI with society's interests, including in the free flow of information that enables the provision of effective and efficient health care services. Such an approach derives from Congress's direction, in 1996, to improve the efficiency and effectiveness of the health care system by encouraging the development of a health information system while taking into account the privacy of IIHI and the uses and disclosures of such information that should be authorized or required.[FN124] In past rulemakings, the Department has made revisions to the Privacy Rule to balance an individual's privacy expectations with a covered entity's need for information for reimbursement and quality purposes.[FN125] As the Department previously explained, “Patient privacy must be balanced against other public goods, such as research and the risk of compromising such research projects if researchers could not continue to use such data.” [FN126] The 2000 Privacy Rule included permissions for regulated entities to disclose PHI under certain conditions, including for judicial and administrative proceedings and law enforcement purposes, because an individual's right to privacy in information about themselves is not absolute. For example, it does not prevent reporting of public health information on communicable diseases, nor does it prevent law enforcement *32986 from obtaining information when due process has been observed.[FN127]

In more recent rulemakings revising the Privacy Rule, the Department has continued its efforts to build and maintain individuals' trust in the health care system while balancing the interests of individuals with those of others. For example, in explaining revisions made as part of the 2013 Omnibus Rule, the Department recognized that covered entities must balance protecting the privacy of health information with sharing health information with those responsible for ensuring public health and safety. [FN128] The Privacy Rule was also revised in 2016 (“2016 Privacy Rule”) in accordance with an administration-wide effort to curb gun violence across the nation.[FN129] The 2016 Privacy Rule was tailored to authorize the disclosure of a limited set of PHI [FN130] for a narrow, specific purpose, that is, to permit only regulated entities that are state agencies or other entities designated by a state to collect and report information to the National Instant Criminal Background Check System (NICS) or a lawful authority making an adjudication or commitment as described by 18 U.S.C. 922(g)(4) to disclose to NICS the identities of individuals who are subject to a Federal “mental health prohibitor,” that disqualifies them from shipping, transporting, possessing, or receiving a firearm. As explained in the 2016 Privacy Rule, the Federal mental health prohibitor applies only to the extent that the individual is involuntarily committed or determined by a court or other lawful authority to be a danger to self or others, or is unable to manage their own affairs because of a mental illness or condition.[FN131] Similar to this final rule, the 2016 Privacy Rule balanced public safety goals with individuals' privacy interests by clearly limiting permissible disclosures to those that are necessary to ensure that individuals are not discouraged from seeking lawful health care, in this case, voluntary treatment for mental health needs.[FN132] In the 2013 Omnibus Rule and 2016 Privacy Rule, the Department ensured that the disclosures were necessary for the public good and were not for the purpose of harming the individual. This approach is consistent with the NCVHS recommendations to the Secretary relating to health information privacy: “The Committee strongly supports limiting use and disclosure of identifiable information to the minimum amount necessary to accomplish the purpose. The Committee also strongly believes that when identifiable health information is made available for non-health uses, patients deserve a strong assurance that the data will not be used to harm them.” [FN133]

Consistent with Congress's directive to promulgate “standards with respect to the privacy of [IIHI]” that, among other things, address the “uses and disclosures of such information that should be authorized or required,” [FN134] the Department recognizes a variety of interests with respect to health information. These include individuals' interests in the privacy of their health information, society's interests in ensuring the effectiveness of the health care system, and other interests of society in using IIHI for certain non-health care purposes. As part of balancing these interests, the Department has also recognized that it may be necessary to afford additional protection to certain types of health information because those types of information are particularly sensitive and often involve highly personal health care decisions. For example, the Department affords special privacy protections to psychotherapy notes. These protections are afforded in part because of the particularly sensitive information those notes contain and in part because of the unique function of these records, which are by definition maintained

separately from an individual's medical record.[FN135] As we previously explained, the primary value of psychotherapy notes is to the specific provider, and the promise of strict confidentiality helps to ensure that the patient will feel comfortable freely and completely disclosing very personal information essential to successful treatment.[FN136] The Department elaborated that even the possibility of disclosure may impede development of the confidential relationship necessary for successful treatment because of the sensitive nature of the problems for which individuals consult psychotherapists and the potential embarrassment that may be engendered by the disclosure of confidential communications made during counseling sessions.[FN137] Therefore, to support the development and maintenance of an individual's trust and protect the relationship between an individual and their therapist, the Privacy Rule permits the disclosure of psychotherapy notes without an individual's authorization only in limited circumstances, such as to avert a serious and imminent threat to health or safety. Those limited circumstances do not include judicial and administrative proceedings or law enforcement purposes unless the disclosure is “necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.” [FN138]

Information about an individual's reproductive health and associated health care is also especially sensitive and has long been recognized as such. As stated in the AMA's Principles of Medical Ethics, the “decision to terminate a pregnancy should be made privately within the relationship of trust between patient and physician in keeping with the patient's unique values and needs and the physician's best professional judgment.” [FN139] NCVHS first noted reproductive health information as an example of a category of health information commonly considered to contain sensitive information in *32987 2006.[FN140] Between 2005 and 2010, NCVHS held nine hearings that addressed questions about sensitive information in medical records and identified additional categories of sensitive information beyond those addressed in Federal and state law, including “sexuality and reproductive health information.” In several letters to the Secretary during that period, NCVHS recommended that the Department identify and define categories of sensitive information, including “reproductive health.” [FN141] In a 2010 letter to the Secretary, NCVHS elaborated that, after extensive testimony on sensitive categories of health information, “reproductive health” should be expanded to “sexuality and reproductive health information,” because:

Information about sexuality and reproductive history is often very sensitive. Some reproductive issues may expose people to political controversy (such as protests from abortion proponents), and public knowledge of an individual's reproductive history may place [them] at risk of stigmatization.” Additionally, individuals may wish to have their reproductive history segmented so that it is not viewed by family members who otherwise have access to their records. Parents may wish to delay telling their offspring about adoption, gamete donation, or the use of other forms of assisted reproduction technology in their conception, and, thus, it may be important to have the capacity to segment these records.[FN142]

The Department did not provide specific protections for certain categories of PHI upon receipt of the recommendation or as part of the 2013 Omnibus Rule because of concerns about the ability of regulated entities to segment PHI and the effects on care coordination. While we recognized the sensitive nature of reproductive health information before this rulemaking, the Department believed that the Supreme Court's recognition of a constitutional right to abortion coupled with the privacy protections afforded by the HIPAA Rules provided the necessary trust to promote access to and quality of health care. As a result of the changed legal landscape for reproductive health care broadly, including abortion, the range of circumstances in which PHI about legal reproductive health care could be sought and used in investigations or to impose liability expanded significantly. Now that states have much broader power to criminalize and regulate reproductive choices—and that some states have already exercised that power in a variety of ways [FN143]—individuals legitimately have a far greater fear that especially sensitive information about lawful health care will not be kept private. This changed environment requires additional privacy protections to help restore the Privacy Rule's carefully-struck balance between individual and societal interests. Because the concerns regarding segmentation and the negative impact on care coordination remain, the Department did not propose and is not establishing a new category of particularly sensitive PHI in this final rule. Instead, as discussed more fully below, the Department is finalizing its proposed purpose-based prohibition against certain uses and disclosures.

B. Developments in the Legal Environment Are Eroding Individuals' Trust in the Health Care System

The Supreme Court's decision in *Dobbs* overturned *Roe v. Wade* [FN144] and *Planned Parenthood of Southeastern Pennsylvania v. Casey*,[FN145] thereby enabling states to significantly restrict access to abortion.[FN146] Following the Supreme Court's

decision, the legal landscape has shifted as laws significantly restricting access to abortion have in fact become effective in some jurisdictions. This change has also led to questions about both the current and future lawfulness of other types of reproductive health care, and therefore, the ability of individuals to access such health care.[FN147] Thus, this shift may interfere with the longstanding expectations of individuals, established by HIPAA and the Privacy Rule, with respect to the privacy of their PHI. [FN148] For example, while the Privacy Rule currently permits, but does not require, uses and disclosures of PHI for certain purposes,[FN149] including when another law requires a regulated entity to make the use or disclosure,[FN150] regulated entities after Dobbs may feel compelled by other applicable law to use or disclose PHI to law enforcement or other persons who may use that health information against an individual, a regulated entity, or another person who has sought, obtained, provided, or facilitated reproductive health care, even when such health care is lawful in the circumstances in which the health care is obtained.[FN151]

As a consequence of these developments in Federal and state law, an individual's expectation of privacy of their health information (irrespective of whether an individual is or was pregnant) is threatened by the potential use or disclosure of PHI to identify persons who seek, obtain, provide, or facilitate lawful reproductive health care. Thus, these developments have created an environment in which individuals are more likely to fear that their PHI will be requested from regulated entities for use against individuals, health care providers, and others, merely because such persons sought, obtained, provided, or facilitated lawful reproductive health care.[FN152] The potential increased demand for PHI for these purposes is not limited to states in which providing or obtaining certain reproductive health care is no longer legal. Rather, the changes in the legal landscape have nationwide implications, not only because of their effects on the relationship between health care providers and individuals, but also because of the potential effects on the flow of health information across state lines. For example, an individual who travels out-of-state to obtain reproductive health care that is lawful under the circumstances in which it is provided may now be reluctant to have that information disclosed to a health care provider in their home state if they ***32988** fear that it may then be used against them or a loved one in their home state. A health care provider may be unable to provide appropriate health care if they are unaware of the individual's recent health history, which could have significant negative health consequences. Individuals and health care providers may also be reluctant to disclose PHI to health plans with a multi-state presence because of concerns that one of those states will seek to obtain that PHI to investigate or impose liability on the individual or the health care provider, even if there is no nexus with that state other than the presence of the health plan in that state. Such reluctance may have significant ramifications for access to reproductive health care, given the cost associated with obtaining such health care, and health care generally.

Additionally, PHI is more likely to be transmitted across state lines as the electronic exchange of PHI increases because it is easier and more efficient to send information electronically. For instance, the Trusted Exchange Framework and Common Agreement (TEFCA) initiative established under the 21st Century Cures Act and the Centers for Medicare & Medicaid Services (CMS) Interoperability and Prior Authorization Final Rule will spur greater use and disclosure of PHI by regulated entities and to health apps and others.[FN153] Different components of a health information exchange/health information network (HIE/HIN) may be located in different states, meaning that the PHI may be transmitted across state lines, and thus affected by laws severely restricting access to reproductive health care, even where both the health care and the recipient of the PHI are located in states where access to such health care is not substantially restricted.

According to commenters, individuals are increasingly concerned about the confidentiality of discussions with their health care providers. As a result, some individuals are not confiding fully in their health care providers, increasing the risk that their medical records will not be complete and accurate, leading to decreases in health care quality and safety. This lack of openness is also likely to affect the information and treatment recommendations health care providers provide to individuals because health care providers will not be sufficiently informed to provide thorough and accurate information and guidance.[FN154]

Individuals are not alone in their fears. Indeed, according to commenters, some health care providers are afraid to provide lawful health care because they are concerned that in doing so, they risk being subjected to investigation and possible liability.[FN155] The Department is aware that some health care providers, such as clinicians and pharmacies, are hesitant to provide lawful health care or lawfully prescribe or fill prescriptions for medications that can result in pregnancy loss, even when the health care or

those prescriptions are intended to treat individuals for other health matters, because of fear of law enforcement action.[FN156] Some health care providers are also not providing individuals with information to address concerns about their reproductive health, even where their communications would be lawful, out of fear of criminal prosecution, civil suit, or loss of their clinical license.[FN157] This may result in individuals making decisions about their health care with incomplete information, which could have serious implications for health outcomes. These fears also increase the risk that individual medical records will not be maintained with completeness and accuracy, which will in turn affect the quality of health care provided to individuals and their safety. Fears about potential prosecution, even when Federal law protects the actions of health care providers, are likely to negatively affect the accuracy of medical records maintained by health care providers and thereby harm individuals.

As explained by commenters and supported by research, these impingements on the privacy of health information about reproductive health care are likely to have a disproportionately greater effect on women, individuals of reproductive age, and individuals from communities that have been historically underserved, marginalized, or subject to discrimination or systemic disadvantage by virtue of their race, disability, social or economic status, geographic location, or environment.[FN158] Historically *32989 underserved and marginalized individuals are also more likely to be the subjects of investigations and other activities to impose liability for seeking or obtaining reproductive health care, even where such health care is lawful under the circumstances in which it is provided.[FN159] They are also less likely to have adequate access to legal counsel to defend themselves from such actions.[FN160] These inequities may be exacerbated where individuals face multiple, intersecting disparities, such as having limited English proficiency [FN161] and disability.[FN162] Such individuals are thus especially likely to be concerned that information they share with their health care providers about their reproductive health care will not remain private. This is particularly true considering the historic lack of trust, negative experiences, and fear of discrimination that many members of historically underrepresented and marginalized communities and communities of color have in the health care system; [FN163] such individuals are more likely to be deterred from seeking or obtaining health care—or from giving their health care providers full information.

Congress contemplated that the Department would need to modify standards adopted under HIPAA's Administrative Simplification provisions and directed the Secretary to review standards adopted under 42 U.S.C. 1320d-2 periodically. [FN164] In accordance with this directive and based on the Department's expertise and analysis and the recent developments in the legal landscape, there is a compelling need to provide additional protections to PHI about lawful reproductive health care. Accordingly, consistent with Congress's directions to the Department, in HIPAA, as amended by Genetic Information Nondiscrimination Act (GINA) and the HITECH Act, to establish standards and requirements for the electronic transmission of certain health information, including the privacy thereof, for the development of a health information system, the Department is restricting certain uses and disclosures of PHI for particular non-health care purposes to provide such protections.

C. To Protect the Trust Between Individuals and Health Care Providers, the Department Is Restricting Certain Uses and Disclosures of PHI for Particular Non-Health Care Purposes

As discussed above, Congress enacted HIPAA to improve the efficiency and effectiveness of the health care system, which includes ensuring that individuals have trust in the health care system. Congress also directed the Department to develop standards with respect to the privacy of PHI as part of its decision to encourage the development of a health information system. To preserve such trust, and to encourage the development and use of a nationwide health information system, it is appropriate and necessary for Federal law and policy to protect the confidentiality of medical records, especially those that are highly sensitive. Accordingly, to protect the trust between individuals and health care providers, this rule restricts certain uses and disclosures of PHI for particular non-health care purposes, i.e., for using or disclosing PHI to conduct a criminal, civil, or administrative investigation into or to impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating *32990 lawful reproductive health care, or to identify any person to initiate such activities.

Information about reproductive health care is particularly sensitive and requires heightened privacy protection. The Department's approach is consistent with efforts across the Federal Government. For example, the Department of Defense (DOD) has recognized such privacy concerns. In a memorandum to DOD leaders, the Secretary of Defense directed the DOD to “[e]stablish additional privacy protections for reproductive health care information” for service members and “[d]isseminate

guidance that directs Department of Defense health care providers that they may not notify or disclose reproductive health information to commanders unless this presumption is overcome by specific exceptions set forth in policy.” [FN165] The Federal Trade Commission (FTC) has also recognized that information about personal reproductive matters is “particularly sensitive” and has committed to using the full scope of its authorities to protect consumers' privacy, including the privacy of their health information and other sensitive data.[FN166] In business guidance, the FTC explained that “[t]he exposure of health information and medical conditions, especially data related to sexual activity or reproductive health, may subject people to discrimination, stigma, mental anguish, or other serious harms.” [FN167]

As discussed above, the Department has long provided special protections for psychotherapy notes because of the sensitivity around this information. However, unlike psychotherapy notes, which by their very nature are easily segregated, reproductive health information is not easily segregated. Additionally, regulated entities generally do not have the ability to segment certain PHI such that regulated entities could afford special protections for specific categories of PHI.[FN168] Where such technology is available, it is generally cost prohibitive and burdensome to implement.[FN169] Therefore, the Department did not propose, and is not finalizing, a newly defined subset of PHI. Creating such a subset would create barriers to disclosing PHI for care coordination because the PHI would need to be segregated from the remaining medical record. Instead, consistent with the Privacy Rule's longstanding overall approach,[FN170] the Department is finalizing a purpose-based prohibition against certain uses and disclosures. This rule seeks to protect individuals' privacy interests in their PHI about reproductive health care and the interests of society in an effective health care system by enabling individuals and licensed health care professionals to make decisions about reproductive health care based on a complete medical record, while balancing those interests with other interests of society in obtaining PHI for certain non-health care purposes.

To assist in effectuating this prohibition, the Department is also requiring regulated entities to obtain an attestation in certain circumstances from the person requesting the use or disclosure stating that the use or disclosure is not for a prohibited purpose. A person (including a regulated entity or someone who requests PHI) who knowingly and in violation of the Administrative Simplification provisions obtains or discloses IIHI relating to another individual would be subject to potential criminal liability.[FN171] Thus, a person who knowingly and in violation of HIPAA falsifies an attestation (e.g., makes a material misrepresentation about the intended uses of the PHI requested) to obtain (or cause to be disclosed) an individual's IIHI could be subject to the criminal penalties provided by the statute.[FN172] Additionally, a regulated entity is subject to potential civil penalties for violations of the HIPAA Rules, including a failure to obtain a valid attestation before disclosing PHI, where an attestation is required.[FN173] The purpose-based prohibition, in concert with the attestation, will restrict the use and disclosure of PHI about lawful reproductive health care where the use or disclosure could harm HIPAA's overall goals of increasing trust in the health care system, improving health care quality, and protecting individual privacy. At the same time, it will allow uses and disclosures that either support those goals or do not substantially interfere with their achievement.

Consistent with the Privacy Rule's approach, the Department is clarifying that the purpose-based prohibition applies only in certain circumstances, recognizing the interests of both the Federal Government and states while also protecting the information privacy interests of persons who seek, obtain, provide, or facilitate lawful reproductive health care. Thus, the Department is finalizing a Rule of ***32991** Applicability that balances the privacy interests of individuals and the interests of society in an effective health care system with those of society in the use of PHI for other non-health care purposes by limiting the new prohibition to certain circumstances.

The Department's experience administering the Privacy Rule, research cited below, our assessment of the needs of individuals and health care providers in light of recent developments to the legal landscape, public comments, and the Regulatory Impact Analysis, in Section VI below, all provide support for the changes finalized in this rulemaking. These changes will improve individuals' confidence in the confidentiality of their PHI and their trust in the health care system, creating myriad benefits for the health care system. Balancing the privacy interests of individuals and the use of PHI for other societal priorities will continue to support an effective health care system, as Congress intended. This final rule will deter the creation of inaccurate and incomplete medical records, which will help to support the provision of appropriate lawful health care. Health care providers base their treatment recommendations on PHI contained within existing medical records, as well as information shared with them

directly by the individual. Thus, where individuals withhold information from their health care providers about lawful health care, health care providers may not be in possession of all of the necessary information to make an informed recommendation for an appropriate treatment plan, which may result in negative health outcomes at both the individual and population level. It will also improve the confidence of individuals, including among the Nation's most vulnerable communities, that they can securely seek or obtain or share that they sought or obtained lawful reproductive health care without that information being used or disclosed for the purpose of investigating or imposing liability on them for seeking or obtaining that lawful health care. By improving individuals' confidence and trust in their relationships with their health care providers, it will make individuals more likely to, for example, comply with preventative health screening recommendations, which will protect against a decline in individual and population health outcomes related to missed preventative health screenings. Additional intangible benefits from increased privacy protections in this area include enhanced support for survivors of rape, incest, and sex trafficking. The new attestation requirement discussed in greater detail below will help to assure regulated entities of their ability to operationalize these changes and avoid exposure to HIPAA liability for impermissible disclosures.

IV. General Discussion of Public Comments

The Department received more than 25,900 comments in response to its proposed rule. Overall, these comments represent the views of approximately 51,500 individuals and 350 organizations. Slightly more than half of the individuals and organizations who shared their views expressed general support for the 2023 Privacy Rule NPRM and its objectives. Less than one percent expressed mixed views. Organizational commenters included professional and trade associations, including those representing medical professionals, health plans, health care providers, health information management professionals, health information management system vendors, release-of-information vendors, employers, epidemiologists, and attorneys. The Department also received comments from advocacy organizations, including those representing patients, privacy advocates, faith-based organizations, and civil rights organizations. The NCVHS also provided comments, as did members of Congress, state, local, and Tribal government officials and public health authorities. Other commenters included health care systems, hospitals, and health care professionals.

A. General Comments in Support of the Proposed Rule

Comment: Many commenters expressed general support for the proposed rule and urged the Department to protect the privacy of individuals by limiting uses and disclosures of PHI for certain purposes where the use or disclosure of information is about reproductive health care that is lawful under the circumstances in which such health care is provided.

Many health care providers and individuals emphasized the importance of trusting relationships between individuals and their health care providers. According to individual commenters, a trusting relationship permits individuals to participate in sensitive and difficult conversations with their health care providers and enables health care providers to furnish high-quality and appropriate health care and to maintain accurate and complete medical records, including records that contain information about reproductive health care.

Many organizations also submitted comments that expressed agreement with the Department's position on the importance of the relationship between HIPAA and the HIPAA Rules and trust between individuals and health care providers. For example, an organization commented that privacy has long been a "hallmark" of medical care and agreed with the Department that Congress recognized this principle when it enacted HIPAA. Some organizations commented that the HIPAA framework of law and rules provides individuals with the necessary trust and confidence to seek reproductive health care without fear of being prosecuted or targeted by law enforcement, including in medical emergencies.

Other commenters stated that a trusting confidential relationship between an individual and a health care provider is an essential prerequisite to the delivery of high-quality health care. They also asserted that protective privacy laws, including HIPAA, help to ensure that individuals do not forgo health care.

Many individuals asserted that the proposed safeguards are urgently needed to provide individuals with the confidence to seek health care. According to the commenters, the proposal would increase the likelihood that pregnant individuals would receive essential health care, thus improving their overall well-being. One commenter expressed support for the proposal because they believe people should not be held liable or face punishment for seeking, obtaining, providing, or facilitating lawful health care. Another commenter expressed concerns that the increase in state legislation targeting reproductive health care has placed significant burdens on physicians and increased the risk of maternal morbidity and mortality for individuals.

A few commenters also expressed agreement with the Department's assertion that the proposed restrictions would clarify legal obligations of regulated entities with respect to the disclosure of PHI for certain non-health related purposes and would enable persons requesting PHI, including health plans, to better understand when such disclosures are permitted.

Response: The Department appreciates these comments and is finalizing the proposed rule with modification, as described in greater detail below. Consistent with HIPAA's goals, this final rule will support the development and maintenance of trust between individuals and their health care providers, encouraging individuals to be forthright with health care providers regarding their health history and providing valuable clarity to the regulated community and individuals concerning their privacy rights with respect to lawfully provided health care. In so doing, the Department helps to support access to health care by increasing individuals' confidence in the privacy of their PHI about lawfully provided reproductive health care. We are taking these actions as a result of our ongoing evaluation of the environment, including the legal landscape, and consistent with the Privacy Rule's longstanding balance of individual privacy and societal interests in PHI for non-health care purposes.

Comment: A wide cross-section of commenters, including individuals, health care providers, patient advocacy organizations, reproductive rights organizations, state law enforcement agencies, and others all agreed that individuals who frequently experience discrimination generally also experience it when seeking health care.

Many of these commenters urged the Department to recognize that there is a trust deficit in relationships between individuals and health care providers in communities that frequently experience discrimination. Many commenters cited scholarly journals and research articles showing that women of color especially suffer poorer medical outcomes, including higher maternal mortality and denial of medical interventions or treatments.

Commenters who answered the Department's request for comment about whether members of “historically underserved and minority communities” are more likely to be the subject of investigations into or proceedings against persons in connection with seeking, obtaining, providing, or facilitating lawful reproductive health care unanimously responded in the affirmative. Some commenters expressed concern about the current legal environment's disproportionately negative effect on the privacy of women and members of marginalized and historically underserved communities and communities of color, such as immigrants who might avoid obtaining health care because of fears that their PHI could be shared with government officials. In general, commenters encouraged the Department to consider the likely negative implications of reduced health information privacy when combined with these disparities on health outcomes for members of marginalized and historically underserved communities and communities of color when crafting the final rule.

Some commenters expressed concern about the current legal environment's disproportionately negative effect on the privacy of members of marginalized and historically underserved communities and communities of color, such as women of color, immigrants and American Indians and Alaska Natives, who might withhold information from health care providers or avoid obtaining health care because of fears that their PHI could be shared with government officials or used to investigate or impose liability on them.

Among commenters that addressed this topic, many supported the Department's proposed purpose-based prohibition. Commenters stated that the proposed rule would help to mitigate medical mistrust of individuals in marginalized and historically underserved communities and communities of color and reduce the racial disparities that result from the increased criminalization of reproductive health care.

Several commenters also addressed the issue of the availability of legal counsel among these communities. A few commenters asserted that individuals who are members of marginalized and historically underserved communities and communities of color are less likely to have access to legal counsel, despite being more likely to be subjects of investigations into or proceedings against persons in connection with obtaining providing or facilitating lawful sexual and reproductive health care and cited to related studies.

Response: We appreciate these comments and thank commenters for sharing these important considerations. As we discussed in the 2023 Privacy Rule NPRM and again here, the experiences of individuals from communities that have been historically underserved, marginalized, or subject to discrimination or systemic disadvantage by virtue of their race, disability, social or economic status, geographic location, or environment have significant negative effects on their relationships with health care providers and their willingness to seek necessary health care. We agree that the current legal landscape has exacerbated the health inequities that these individuals encounter when seeking reproductive health care services. The Department expects that the steps we have taken in this rule will meaningfully strengthen the privacy of PHI about lawful reproductive health care, and as a result, will help to mitigate the exacerbation of health disparities for members of marginalized and historically underserved communities and communities of color.

The Department is actively working to reduce health disparities. In recent months, we released a new plan to address language barriers and strengthen language access in health care,[FN174] and issued three proposed rules to address health disparities: one to revise existing regulations to strengthen prohibitions against discrimination on the basis of a disability in health care and human services programs; [FN175] another to issue new regulations to advance non-discrimination in health and human service programs for the LGBTQI+ community; [FN176] and a third to revise existing regulations to prohibit discrimination on the basis of race, color, national origin, sex, age, and disability in a range of health programs.[FN177] The Department will continue to work to address these concerns, ensure that individuals have access to and do not forgo necessary health care, and build individuals' trust that health care providers can and will protect the privacy of individuals' sensitive health information.

Comment: A few commenters agreed with the Department's position that the proposed rule would appropriately protect individuals against growing threats to their privacy with respect to PHI about reproductive health care while permitting states to conduct law enforcement activities.

Response: The Privacy Rule always has and continues to balance privacy interests and other societal interests by permitting disclosures of PHI to support *32993 public policy goals, including disclosures to support certain criminal, civil, and administrative law enforcement activities; the operation of courts and tribunals; health oversight activities; the duties of coroners and medical examiners; and the reporting of child abuse, domestic violence, and neglect to appropriate authorities. We appreciate these comments that recognized the growing threat to the privacy of PHI and the need to strike an appropriate balance between ensuring health care privacy and conducting law enforcement activities. We are finalizing the proposed rule with modification as described in greater detail below.

B. General Comments in Opposition to the Proposed Rule

Comment: Several commenters generally opposed the proposed rule because of their opposition to certain types of reproductive health care. Many commenters opposed the proposed rule generally because they believed that it would harm women and children. Other commenters expressed concern that the proposals would increase administrative burdens and costs for health care providers; impede parental rights; prevent mandatory reporting of child abuse or abuse, domestic violence, and neglect; infringe upon states' rights; thwart law enforcement investigations; inhibit disclosures for public health activities; and protect those who engage in unlawful activities.

Response: The modifications to the Privacy Rule in this final rule directly advance Congress' directive in HIPAA to improve the efficiency and effectiveness of the health care system by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information,[FN178] including

a standard for the privacy of IIHI that, among other things, addresses the “uses and disclosures of such information that should be authorized or required.” [FN179] As discussed in greater detail elsewhere in this final rule, a trusting relationship between individuals and health care providers is the foundation of effective health care. A primary goal of the Privacy Rule is to ensure the privacy of an individual's PHI while permitting necessary uses and disclosures of PHI that enable high-quality health care and protect the health and well-being of all individuals, including women and children, and the public.

From the outset, the Department structured the Privacy Rule to ensure that individuals do not forgo lawful health care when needed—or withhold important information from their health care providers that may affect the quality of health care they receive out of a fear that their sensitive information would be revealed outside of their relationship with their health care provider. The Department has long been committed to protecting the privacy of PHI and providing the opportunity for an authentic, trusting relationship between individuals and health care providers. As we discussed in the 2023 Privacy Rule NPRM and again here, this final rule will help engender trust between individuals and health care providers and confidence in the health care system. We believe that this confidence will eliminate some of the burdens health care providers face in providing high-quality health care, encourage health care providers to accurately document PHI in an individual's medical record, and encourage individuals to provide health care providers with their complete and accurate health history, all of which will ultimately support better health outcomes. Nothing in this final rule sets forth a particular standard of care or affects the ability of health care providers to exercise their professional judgment.

This final rule protects the relationship between individuals and health care providers by protecting the privacy of PHI in circumstances where recent legal developments have increased concerns about that information being used and disclosed to harm persons who seek, obtain, provide, or facilitate reproductive health care under circumstances in which such health care is lawful, while continuing to permit uses and disclosures that confer other social benefits. It is narrowly tailored and respects the interests of both states and the Department. The final rule continues to permit regulated entities to use or disclose PHI to comply with certain mandatory reporting laws, for public health activities, and for law enforcement purposes when the uses and disclosures are compliant with the applicable provisions of the Privacy Rule.

Further, consistent with the longstanding operation of the Privacy Rule, this final rule requires that, in certain circumstances, regulated entities obtain information from persons requesting PHI, such as law enforcement, before the regulated entities may use or disclose the requested PHI. The Department recognizes that this final rule may increase the burden on those persons making requests for PHI, such as federal and state law enforcement officials, by requiring, in certain circumstances, that regulated entities obtain more information from such persons than previously required, and may, at times, prevent regulated entities from using or disclosing PHI that they previously would have been permitted to use or disclose. For example, the Department recognizes that situations may arise where a regulated entity reasonably determines that reproductive health care was lawfully provided, while at the same time, the person requesting the PHI (e.g., law enforcement) reasonably believes otherwise. In such circumstances, where the regulated entity provided the reproductive health care, and upon receiving a request for the PHI for a purpose that implicates the prohibition, reasonably determines that the provision of reproductive health care was lawful, the final rule would prohibit the regulated entity from disclosing PHI for certain types of investigations into the provision of such health care. This constitutes a change from the current Privacy Rule, under which a regulated entity is permitted, but not required, to make a use or disclosure under [45 CFR 164.512\(f\)](#) of information that is “relevant and material to a legitimate” law enforcement inquiry, provided that certain conditions are met; these conditions include, for example, that the request is specific and limited in scope to the extent reasonably practicable given the purpose for which the information is sought.[FN180] Similarly, the Department acknowledges that, where the regulated entity did not provide the reproductive health care that is the subject of the investigation or imposition of liability, the Rule of Applicability and Presumption, discussed below, may require regulated entities to obtain additional information, that is, factual information that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided, from persons requesting PHI before using or disclosing the requested PHI.

Consistent with HIPAA and the Department's longstanding approach in the Privacy Rule, the Department is finalizing an approach that strikes an appropriate balance between the privacy interests of individuals and the interests of law enforcement,

and private parties afforded legal rights of action, in *32994 obtaining PHI for certain non-health care purposes. While this approach may adversely affect particular interests of law enforcement, and private parties afforded legal rights of action, in some cases, the Department believes that the final rule best balances these competing interests by enhancing privacy protections without unduly interfering with legitimate law enforcement activities and does so in a manner that is consistent with the approach taken elsewhere in the Privacy Rule. As explained above, individual privacy interests are especially strong where individuals seek lawful reproductive health care. In particular, individuals may forgo lawful health care or avoid disclosing previous lawful health care to providers because they fear that their PHI will be disclosed. The Department believes these concerns are exacerbated by the prospect of state investigations into, and resulting intimidation and criminalization of, health care providers for providing lawful reproductive health care, as well as state laws encouraging state residents to sue persons who facilitate individuals' access to legal health care. The final rule addresses these interests by protecting privacy in situations where the reproductive health care at issue is especially likely to be lawful under the circumstances in which such health care was provided. Where a regulated entity receives a request for PHI about reproductive health care that the regulated entity provided, such health care is likely to be lawful where the regulated entity reasonably determines, based on all information in its possession, that such health care was lawful under the circumstances in which it was provided. Similarly, where a regulated entity receives a request for PHI about reproductive health care that the regulated entity did not provide, such health care is likely to be lawful where law enforcement is unable to provide factual information that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided.

The Department recognizes that, in some cases, the approach adopted in this final rule may inadvertently prohibit the disclosure of PHI about reproductive health care that was unlawfully provided, such as where a health care provider reasonably but incorrectly determines that the reproductive health care it provided was lawful under the circumstances in which such health care was provided. This is similar to how the Privacy Rule has always potentially prevented the use or disclosure of PHI that could be useful to law enforcement in certain circumstances because the request for PHI does not meet the conditions of the applicable permission. Nevertheless, given the importance of protecting individual privacy in this area, the Department has determined that the final rule adopts the appropriate balance between individual privacy and the interests of other persons, such as law enforcement. Specifically, the Department believes that the benefits to individual privacy of a broadly protective rule outweigh the benefits to societal interests in the use or disclosure of PHI from a narrower rule. While a narrower rule would more broadly permit disclosures related to PHI that might concern reproductive health care that is not lawful under the circumstances in which it is provided, such a rule would inadvertently permit more disclosures of PHI about lawful reproductive health care. Accordingly, the Department concludes that the final rule must be sufficiently broad to protect against such disclosures, given the paramount importance of individual privacy in this area.

Moreover, as explained above, individual privacy interests are paramount to promote free and open communication between individuals and their health care providers, thereby ensuring that individuals receive high-quality care based on their accurate medical history. Society has long recognized that information exchanged as part of a specific relationship for which trust is paramount should be entitled to heightened protection (e.g., marital privilege, attorney-client privilege, doctor-patient privilege). Similarly, this final rule seeks to address situations where privacy interests are especially important, based both on the content of the information that is protected from disclosure (concerning lawful reproductive health care) and the context in which that information is shared (concerning a trust-based relationship between individuals and their health care providers).

In contrast, the potential adverse effects of this final rule on other interests, such as those of law enforcement, are limited by the narrow scope of this final rule. This final rule does not seek to prohibit disclosures of PHI where the request is for reasons other than investigating or imposing liability on persons for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided. For example, as explained in the NPRM and below, the final rule does not prohibit the use or disclosure of PHI for investigating alleged violations of the Federal False Claims Act or a state equivalent; conducting an audit by an Inspector General aimed at protecting the integrity of the Medicare or Medicaid program where the audit is not inconsistent with this final rule; investigating alleged violations of Federal nondiscrimination laws or abusive conduct, such as sexual assault, that occur in connection with reproductive health care; or determining whether a person or entity violated 18 U.S.C. 248 regarding freedom of access to clinic entrances. In each of these

cases, the request is not made for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

Even when the request is for the purpose of investigating or imposing liability on the mere act of seeking, obtaining, providing, or facilitating reproductive health care, this final rule does not seek to prohibit disclosures of PHI about reproductive health care that is not lawful under the circumstances in which it was provided. Thus, in most situations involving reproductive health care that is not lawful under the circumstances in which it is provided, this final rule will not prevent the use or disclosure of PHI to investigate or impose liability on persons for such legal violations, provided such disclosures are otherwise permitted by the Privacy Rule. Moreover, where a regulated entity did not provide the reproductive health care at issue, this final rule prohibits the use or disclosure of PHI where the person making the request does not provide sufficient information to overcome the presumption of legality. In such cases, law enforcement agencies and other persons have a reduced interest in obtaining such PHI where the information does not demonstrate to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the circumstances in which such health care was provided.

This final rule does not prohibit the use or disclosure of PHI to investigate or impose liability on persons where reproductive health care is unlawful under the circumstances in which it is provided. Instead, the final rule prohibits the use or disclosure of PHI in narrowly tailored circumstances (i.e., where the use or disclosure is to conduct an investigation or impose liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that ***32995** is lawful under the circumstances in which such health care is provided, or to identify a person for such activities). For example, once this final rule is in effect, a covered health care provider may still disclose PHI to a medical licensing board investigating a health care provider's actions related to their obligation to report suspected elder abuse, assuming the disclosure meets the conditions of an applicable Privacy Rule permission. This is because the final rule does not bar the use or disclosure of PHI for health oversight purposes, which is unrelated to the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

Additionally, even where the final rule prohibits the use or disclosure of PHI to investigate potentially unlawful reproductive health care (i.e., where a regulated entity reasonably determines that the reproductive health care they provided was lawful, or where the presumption of legality is not overcome), law enforcement retains other ways of investigating reproductive health care that they suspect may have been unlawfully provided. For example, law enforcement retains the use of other traditional and otherwise lawful investigatory means for obtaining information, such as conducting witness interviews and accessing other sources of information not covered by HIPAA. The final rule is therefore tailored to protect the relationship between individuals and their health care providers specifically, while leaving unaffected law enforcement's ability to conduct investigations using information from other sources.

With respect to commenters' concerns about parental rights, this final rule also does not interfere with the ability of states to define the nature of the relationship between a minor and a parent or guardian.

Comment: A few commenters that expressed negative views asserted that the proposed rule exceeded the Department's statutory authority under HIPAA or was beyond the Department's rulemaking authority. Some commenters stated that the rulemaking was arbitrary and capricious and would make it difficult for law enforcement to investigate reproductive health care and engage in health oversight activities and would require health care providers to provide certain types of health care against which they have objections. Some commenters expressed concern about the balance of powers between the states and the federal government. Other commenters suggested that the proposals preempt state laws serving public health, safety, and welfare.

Response: As discussed above, Congress explicitly stated that the purpose of HIPAA's Administrative Simplification provisions was to improve the efficiency and effectiveness of the health care system. For the health care system to be effective, individuals must trust that information that they share with health care providers about lawful health care will remain private. Accordingly, since their inception, the HIPAA Rules have required that regulated entities narrowly tailor disclosures to law enforcement to protect an individual's privacy.[FN181] While the Department is adopting an approach in this final rule that is more protective of privacy interests than the current Privacy Rule in certain circumstances, these changes are necessary to appropriately

balance privacy interests and the interests of law enforcement, and private parties afforded legal rights of action, in light of the changing legal environment. This is discussed in detail above. In both the 2023 Privacy Rule NPRM and this final rule, the Department cited to multiple studies documenting the real-world harm to health and health care in the changing legal environment. As explained above, the Department acknowledges that this final rule may affect certain state interests in obtaining PHI to investigate potentially unlawful reproductive health care, but the Department has tailored the final rule to strike the appropriate balance between privacy interests and state interests. This final rule limits the potential harm to individuals, health care providers, and others resulting from the disclosure of PHI to investigate or punish individuals for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided. We emphasize that nothing in this rule or any of the HIPAA Rules requires a health care provider to provide any type of health care, including any type of reproductive health care.

Comment: Several commenters asserted that the proposed rule would impede states' enforcement of their own laws, including those concerning sexual assault and sex trafficking. Many commenters opposed the proposed rule because they believed it would inhibit the ability of states to investigate or enforce laws prohibiting minors from obtaining certain types of health care and prevent the commenters from reporting minors who they believe are coerced into obtaining such health care to authorities.

Response: This rule does not prohibit the disclosure of PHI for investigating allegations of or imposing liability for sexual assault, sex trafficking, or coercing minors into obtaining reproductive health care. Rather, this final rule modifies the existing HIPAA Privacy Rule standards by prohibiting uses and disclosures of PHI to investigate or impose liability on individuals, regulated entities, or other persons for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such reproductive health care is provided, or to identify any person to investigate or impose liability on them for such purposes. Accordingly, requests for the disclosure of PHI to investigate such allegations of or impose liability for such crimes do not fall within the final rule's prohibition, and the presumption of lawfulness likewise would not be triggered because the prohibition would not apply. A regulated entity therefore would not be prohibited from disclosing an individual's PHI when subpoenaed by law enforcement for the purpose of investigating such allegations, assuming that law enforcement provided a valid attestation and met the other conditions of the applicable permission.

Moreover, as explained above, the final rule is tailored to prohibit disclosures related to lawful reproductive health care, thereby reducing the interference with law enforcement interests to create an appropriate balance with privacy interests.

Comment: Some states expressed concern that the proposed rule would intrude into areas where the HIPAA Rules have previously acknowledged state control, such as enforcement of state and local laws, regulation of the practice of health care, and reporting of abuse.

Response: This final rule balances the interests of individuals in the privacy of their PHI and of society in an effective health care system with those of society in obtaining PHI for certain non-health care purposes. The Privacy Rule always has and continues to permit disclosures of PHI to support public policy goals, including disclosures to support criminal, civil, and administrative law enforcement activities; the operation of courts and tribunals; health oversight activities; the duties of coroners and medical examiners; and the reporting of child abuse, domestic violence, and neglect to appropriate authorities. As explained above, while the final rule adopts an approach that is more ***32996** protective of privacy interests in certain circumstances than the previous Privacy Rule, the final rule continues to balance the interests that HIPAA Rules have long sought to protect with those of society in PHI.

C. Other General Comments on the Proposed Rule

Comment: Commenters urged the Department to provide enhanced privacy protections for health information that is not covered by existing frameworks or specifically addressed in the proposed rule. A few professional associations expressed support for revising the Privacy Rule to provide stronger protection for the privacy of reproductive health care information and urged the Department to modify the Privacy Rule to provide even stronger protections than those proposed in the 2023 Privacy Rule NPRM.

Response: The Department's authority under HIPAA is limited to protecting the privacy of PHI that is maintained or transmitted by covered entities and, in some cases, their business associates. Specific modifications to the Privacy Rule to protect the privacy of PHI are described in greater detail below. Consistent with the Department's longstanding approach with respect to the Privacy Rule, the modifications we are finalizing in this rule strike a balance between protecting an individual's right to health information privacy with the interests of society in permitting the disclosure of PHI to support the investigation or imposition of liability for unlawful conduct. In particular, the final rule does not prohibit the disclosure of PHI about reproductive health care that was unlawfully provided, because an individual's privacy interests in reproductive health care that is not lawful (e.g., a particular type of reproductive health care that is provided by a nurse practitioner in a state that requires that type of reproductive health care to be provided by a physician) are comparatively lower than a state's interests in investigating and imposing liability on persons for unlawful reproductive health care. We will continue to monitor legal developments and their effects on individual privacy as we consider the need for future modifications to the Privacy Rule.

Comment: Several commenters questioned how the proposed rule would affect their current business associate and data exchange agreements.

Response: The modifications in this final rule may require regulated entities to revise existing business associate agreements where such agreements permit regulated entities to engage in activities that are no longer permitted under the revised Privacy Rule. Regulated entities must be in compliance with the provisions of this rule by December 23, 2024.

Comment: A few commenters requested clarification of whether minors and legal adults have the same protections under the Privacy Rule and whether this rule would alter existing protections.

Response: The final rule does not change how the Privacy Rule applies to adults and minors. Thus, all of the protections provided to PHI by this final rule apply equally to adults and minors. For example, under this final rule, a regulated entity is prohibited from using or disclosing a minor's PHI for the purposes prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#). The Privacy Rule generally permits a parent to have access to the medical records about their child as their minor child's personal representative when such access is consistent with state or other law, with limited exceptions.[FN182] Additional information about how the Privacy Rule applies to minors can be found at [45 CFR 164.502\(g\)](#) and on the OCR website.[FN183]

Comment: Many commenters urged the Department to take an educational approach, rather than a punitive one, with respect to enforcement against regulated entities. In addition, many commenters addressed the need for resources and education for successful implementation of the proposed changes to the Privacy Rule. They called for the Department to collaborate with and educate regulated entities, individuals, and others affected by the proposed revisions, such as law enforcement, as well as for the Department to partner with other Federal agencies and state governments to conduct the education. Some suggested that educational resources should include multiple media formats and a centralized platform.

Response: The Department frequently issues non-binding guidance and conducts outreach to help regulated entities achieve compliance. We appreciate these recommendations and will consider these topics for future guidance. Regulated entities are expected to comply with the Privacy Rule as revised once the compliance date has passed.

V. Summary of Final Rule Provisions and Public Comments and Responses

The Department is modifying the Privacy Rule to strengthen privacy protections for individuals' PHI by adding a new category of prohibited uses and disclosures of PHI. This final rule prohibits a regulated entity from using or disclosing an individual's PHI for the purpose of conducting a criminal, civil, or administrative investigation into or imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided, meaning that it is either: (1) lawful under the circumstances in which such health care is provided and in the state in which it is provided; or (2) protected, required, or authorized by Federal law, including the United States Constitution, regardless of the state in which such health care is provided. In both of these circumstances,

as explained above, the interests of the individual in the privacy of their PHI and of society in ensuring an effective health care system outweighs those of society in the use of PHI for non-health care purposes. To operationalize this modification, the Department is revising or clarifying certain definitions and terms that apply to the Privacy Rule, as well as other HIPAA Rules. This final rule also prohibits a regulated entity from using or disclosing an individual's PHI for the purpose of identifying an individual, health care provider, or other person for the purpose of initiating such an investigation or proceeding against the individual, a health care provider, or other person in connection with seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided.

To effectuate these proposals, the Department is finalizing conforming and clarifying changes to the HIPAA Rules. These changes include, but are not limited to, clarifying the definition of “person” to reflect longstanding statutory language defining the term; adopting new definitions of “public health” surveillance, investigation, or intervention, and “reproductive health care”; adding a new category of prohibited uses and disclosures; clarifying that a regulated entity may not decline to recognize a person as a personal representative for the purposes of the Privacy Rule because they provide or facilitate reproductive health care for an individual; imposing a new ***32997** requirement that, in certain circumstances, regulated entities must first obtain an attestation that a requested use or disclosure is not for a prohibited purpose; and requiring modifications to covered entities' NPPs to inform individuals that their PHI may not be used or disclosed for a purpose prohibited under this final rule.

The Department's section-by-section description of the final rule is below.

A. Section 160.103 Definitions

1. Clarifying the Definition of “Person”

HIPAA does not define the term “person.” [FN184] The HIPAA Rules have long defined “person” to mean “a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.” [FN185] This meaning was based on the definition of “person” adopted by Congress in the original SSA, as an “individual, a trust or estate, a partnership, or a corporation.” [FN186]

In 2002, Congress enacted **1 U.S.C. 8**, which defines “person,” “human being,” “child,” and “individual.” [FN187] The statute specifies that these definitions shall apply when “determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative bureaus and agencies of the United States.” [FN188] The Department understands **1 U.S.C. 8** to provide definitions of “person,” “individual,” and “child” that do not include a fertilized egg, embryo, or fetus, and are consistent with the Department's understanding of those terms, as used in the SSA, HIPAA, and the HIPAA Rules.

The Department proposed to clarify the term “natural person” in a manner consistent with **1 U.S.C. 8**. [FN189] Thus, the Department proposed to clarify that all terms subsumed within the definition of “natural person,” such as “individual,” [FN190] are limited to the confines of the term “person.” [FN191] As discussed in the 2023 Privacy Rule NPRM, the purpose of this proposal was to better explain to regulated entities and other stakeholders the parameters of an “individual” whose PHI is protected by the HIPAA Rules.

Many individuals and organizations commented on the proposal to clarify the definition “person.” Organizational commenters, including professional associations representing health care providers, advocacy groups, and academic departments, generally supported the proposal. Several commenters applauded the proposed clarification because they believed it would limit disclosures of PHI in cases where no individual has been harmed.

Most opponents of the proposed clarification were individuals participating in form letter campaigns who expressed concern that the proposal might diminish access to prenatal care. Others asserted that the proposed clarification would contradict or conflict with existing laws, such as mandatory reporting laws and Federal statutes that rely upon a different definition of “person.”

The final rule adopts the proposed clarification of the definition of person, to mean a “natural person (meaning a human being who is born alive), trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.” Therefore, an “individual,” “child,” or “victim” (e.g., a victim of crime) under the HIPAA Rules must be a natural person. As we explained in the 2023 Privacy Rule NPRM, this clarification is consistent with the SSA, HIPAA, and [1 U.S.C. 8](#). This clarification applies only to regulations issued pursuant to the Administrative Simplification provisions of HIPAA.[FN192]

This clarification is consistent with the Privacy Rule's longstanding definitions of “person” [FN193] and “individual,” [FN194] as applied to Privacy Rule provisions permitting certain types of reports or other disclosures of PHI. For example, a regulated entity is permitted to disclose PHI about an individual who the regulated entity reasonably believes to be a victim of abuse, neglect, or domestic violence only where the individual is a “natural person.” [FN195] In addition, because a “victim” necessarily is a natural person, the permission to disclose PHI to avert a serious threat to health or safety at [45 CFR 164.512\(j\)\(i\)](#) does not permit disclosures when the perceived threat does not involve the health or safety of a natural person or the public, or when an individual has not caused serious physical harm to a natural person.

Comment: Many organizational commenters expressed support for the proposal to clarify the definition of “person.”

One commenter stated that this clarification should prevent law enforcement from attempting to avoid the proposed prohibition. According to another commenter, this proposed clarification is crucial as stakeholders adapt to the current reproductive health landscape.

Several commenters expressed support for the Department's proposal but requested additional clarifications. For example, one commenter recommended that the Department clarify whether the definition would preempt state laws.

Response: We take the opportunity to emphasize here that the clarification only applies to the HIPAA Rules and explains certain terms that apply to the permissions for uses and disclosures of PHI by regulated entities. We do not believe it is necessary to further clarify the final regulatory text because the current definition remains unchanged other than to incorporate the plain wording of [1 U.S.C. 8](#).

Comment: A few commenters expressed opposition to the Department's proposed clarification of “person” as tantamount to eliminating legal protections for and recognition of categories of human beings based on developmental stage. Some commenters maintained that the proposed clarification of “person” was inaccurate.

Several commenters opposed the proposed clarification of “person” because it would affect the provision of prenatal care.

A few commenters asserted that the proposed clarification would prevent the collection of medical information about reproductive health care for ***32998** important purposes, such as public health and research.

Response: We are clarifying the definition of person consistent with applicable Federal law only for the purpose of applying HIPAA's Administrative Simplification provisions. This clarification will not affect how the term “person” is applied for purposes of other laws, affect any rights or protections provided by any other law, or affect standards of health care, including prenatal care.

This final rule does not affect the reporting of vital statistics, nor does it affect the ability of regulated entities to use and disclose PHI for research. The Privacy Rule's standards for uses and disclosures for public health surveillance, investigations, and interventions, or for health oversight activities, are discussed elsewhere.

Comment: Several commenters requested additional clarifications to the Department's proposed clarification of “person.” A few commenters asserted that the proposed clarification would be overly expansive. Most of these same commenters disagreed with

the Department's interpretation of 1 U.S.C. 8.[FN196] Commenters asserted that the clarification was inconsistent or conflicted with other laws.

Response: The clarified definition of person that we are finalizing in this rule does not change the Department's interpretation of the term or change definitions under other law, such as state law. It also is consistent with Federal law, including 1 U.S.C. 8, which specifically applies to Federal regulations, and other examples cited by commenters. For example, both GINA and the Privacy Rule protect the genetic information of a fetus carried by a pregnant individual as the PHI of the pregnant individual. [FN197]

The other laws cited by commenters address policy concerns that are different from those health information privacy issues addressed under HIPAA and do not address personhood. Even if those statutes did adopt different understandings of who is a “person,” the Department has the authority to clarify or define terms that apply to the Administrative Simplification regulations issued pursuant to HIPAA. Additionally, the definition in the final rule of 1 U.S.C. 8 is appropriate because it is consistent with the Department's longstanding interpretation of the term in the context of HIPAA's Administrative Simplification provisions and associated regulations. Many Federal and state laws operate with differing definitions of common terms, to which existing legal standards that govern how such differences are to be interpreted would apply.[FN198]

Comment: A few commenters asserted that the proposal would expand minors' access to hormone therapy or surgeries without requiring parental consent.

Response: The final rule's clarification to define the term “person” does not affect the ability of a parent to make decisions related to health care for an individual who is an unemancipated minor,[FN199] and nothing in this rule dictates a standard of care. The application of this definition is limited to the HIPAA Rules.

Comment: A few commenters asserted that the proposed clarification would help to prevent the misapplication of child abuse laws to individuals who engage in certain behaviors while pregnant (e.g., use of an illicit substance or alcohol). Several other commenters expressed concern that this definition would limit the ability of a regulated entity to apply the Privacy Rule permission to use or disclose PHI to prevent a serious and imminent threat to a fertilized egg, embryo, or fetus.

Response: Under this final rule, a regulated entity would continue to be permitted to disclose PHI about an individual who the covered entity reasonably believes is a victim of child abuse or neglect, consistent with 45 CFR 164.512(b)(1)(ii), or a victim of abuse, neglect, or domestic violence, consistent with 45 CFR 164.512(c), to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence under the circumstances set forth under 45 CFR 164.512(c) where the individual meets the clarified definition of person. The Privacy Rule permission concerning serious and imminent threats [FN200] applies to threats to a person, consistent with the definition as clarified by this final rule, or the public.

2. Interpreting Terms Used in Section 1178(b) of the Social Security Act Reporting of Disease or Injury, Birth, or Death

Section 1178(a) of the SSA provides that HIPAA generally preempts contrary state laws with certain limited exceptions, such as those described in section 1178(b).[FN201] Specifically, section 1178(b) excepts from HIPAA's general preemption authority laws that provide for certain public health reporting, such as the reporting of disease or injury, birth, or death.[FN202] HIPAA does not define the terms in section 1178(b) that govern the scope of this exception to HIPAA's general preemption authority, nor has the Department previously defined such terms through rulemaking.

The Department recognizes that such public health reporting activities are an important means of identifying threats to the health and safety of the public. Accordingly, when a public health authority [FN203] has furnished documentation of its authority [FN204] to collect or receive such information, the Privacy Rule permits a regulated entity, without an individual's authorization, to use or disclose PHI to specified persons for public health activities.[FN205] These activities include all of the vital statistics reporting activities described in section 1178(b), including reporting of diseases and injuries, birth, or death.[FN206]

The Department proposed to interpret in preamble key terms used in section 1178(b) to clarify when HIPAA's general preemption authority applies. Specifically, the Department proposed an interpretation of section 1178(b) that would clarify that HIPAA's general preemption authority applies to laws that require regulated entities to use or disclose PHI for a purpose that would be prohibited under the proposed rule. Under this interpretation, the Privacy Rule permission to use or disclose PHI without an individual's authorization for the reporting of disease or injury, birth, or death [FN207] would not permit the use or disclosure of PHI for a criminal, civil, or administrative investigation into or proceeding against a person in connection with seeking, obtaining, ***32999** providing, or facilitating reproductive health care. The Department did not intend this clarification to prevent disclosures of PHI from regulated entities to public health authorities for public health purposes that have been and continue to be permitted under the Privacy Rule. Nor did the Department intend for this proposed clarification to prevent disclosures of PHI by regulated entities under other permissions in the Privacy Rule, such as for law enforcement purposes,[FN208] when made consistent with the conditions of the relevant permission and where the purpose of the disclosure is not one for which a use or disclosure would have been prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#) as proposed.

The Department did not propose to define “disease or injury,” “birth,” or “death,” because we believed that these terms, when read with the definition of “person” and in the broader context of HIPAA, would exclude information about reproductive health care without the need for further clarification.[FN209] However, the Department invited public comment on whether it would be beneficial to make such clarification.

Few commenters addressed interpretation of these terms. Some commenters expressed concern that the Department's interpretation would prevent beneficial public health reporting about certain types of reproductive health care, while others requested that the Department prohibit public health reporting about certain types of reproductive health care. Some commenters on this issue agreed with the Department's interpretation and clarification of the terms used in 1178(b). Several of these commenters requested that the Department define or clarify these terms because reporting standards are inconsistent across states.

The Department declines to add definitions for “disease or injury,” “birth,” or “death” to the Privacy Rule in this final rule. However, we offer the discussion below to provide additional context on our interpretation of these terms.

At the time of HIPAA's enactment, state laws provided for the reporting of disease or injury, birth, or death by covered health care providers and other persons.[FN210] State public health reporting systems were well established and involved close collaboration between the state, local, or territorial jurisdiction and the Federal Government.[FN211] Reports generally were made to public health authorities or, in some specific cases, law enforcement (e.g., reporting of gunshot wounds).[FN212] Similar public health reporting systems continue to exist today.

Reporting of “disease or injury” commonly refers to diagnosable health conditions reported for limited purposes such as workers' compensation, tort claims, or communicable or other disease or injury tracking efforts. States, territories, and Tribal governments require health care providers (e.g., physicians, laboratories) and some others (e.g., medical examiners, coroners, veterinarians, [FN213] local boards of health) to report cases of certain diseases or conditions that affect public health, such as coronavirus disease 2019 (COVID-19), malaria, and foodborne illnesses.[FN214] Such reporting enables public health practitioners to study and explain diseases and their spread, along with determining appropriate actions to prevent and respond to outbreaks.[FN215] States also require health care providers to report incidents of certain types of injuries, such as those caused by gunshots, knives, or burns.[FN216] Various Federal statutes use the phrase “disease or injury” similarly to refer to events such as workplace injuries for purposes of compensation.[FN217]

The limited meaning given to the terms “disease” and “injury” for purposes of public health reporting is clear from HIPAA's broader context. For instance, interpreting “injury” reporting to include disclosures about all instances of suspected criminal abuse would render the specific permission to report “child abuse” superfluous.[FN218] And interpreting “disease” reporting to include disclosures about any sort of disease for any purpose would both eviscerate HIPAA's general provisions protecting

PHI and make superfluous the statutory requirement to not invalidate laws providing for public health surveillance, or public health investigation or intervention. For example, “disease management activities” constitute “health care” under the Privacy Rule. As such, a broad interpretation of “disease or injury” reporting could make potentially all the health records detailing a particular individual’s treatment for any disease or injury disclosable to a public health authority or others unrelated to the health care.[FN219] Consequently, the Department has long understood “disease or injury” to narrowly refer to diagnosable health conditions reported for limited purposes such as workers’ compensation, tort claims or in compliance with Federal laws that require states to conduct surveillance of specific diseases and injuries related to public health or Federal funding.[FN220]

With respect to reporting of “births” and “deaths,” such vital statistics are reported by health care providers to the vital registration systems operated in ***33000** various jurisdictions [FN221] legally responsible for the registration of vital events. [FN222] State laws require birth certificates to be completed for all births, and Federal law mandates the national collection and publication of births and other vital statistics data.[FN223] Tracking and reporting death is a complex and decentralized process with a variety of systems used by more than 6,000 local vital registrars.[FN224] When HIPAA was enacted, the Model State Vital Statistics Act and Regulations, which is followed by most states,[FN225] included distinct categories for “live births,” “fetal deaths,” and “induced terminations of pregnancy,” with instructions that abortions “shall not be reported as fetal deaths.” [FN226] In light of that common understanding at the time of HIPAA’s enactment, it is clear that the reporting of abortions is not included in the category of reporting of deaths for the purposes of HIPAA and does not fall within the scope of state death reporting activities that Congress specifically designated as excepted from preemption by HIPAA.

More generally, while Congress exempted certain “[p]ublic health” laws from preemption,[FN227] Congress chose not to create a general exception for criminal laws or other laws that address the disclosure of information about similar types of activities outside of the public health context.

For all these reasons, state laws requiring the use or disclosure of PHI for the purpose of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying a person for such activities, are subject to HIPAA’s general preemption provision. Similarly, the Privacy Rule’s public health provisions that permit the disclosure of PHI for the reporting of disease or injury, birth, or death do not include permission to use or disclose PHI for the purpose of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying a person for such activities. This general distinction between public health activities and investigation and enforcement activities is not limited to reproductive health care. Nevertheless, as discussed elsewhere in this final rule, the Department has chosen to strike a balance between privacy interests and other public policy interests. Consistent with the Department’s longstanding approach that has allowed disclosures for law enforcement purposes in certain circumstances, the new prohibitions set forth in this rule apply only to lawful reproductive health care. State authorities cannot rely on the Privacy Rule’s permissions for disclosures related to disease or injury, birth, or death to obtain PHI for the purpose of investigating or imposing liability for the provision of reproductive health care. However, as discussed above, state authorities may be able to invoke other permissions, such as the permission for disclosures for law enforcement purposes, to obtain such PHI where such disclosure is to investigate or impose liability on a person when the reproductive health care at issue is unlawful under the circumstances in which it is provided.

Comment: A few commenters expressed support for the Department’s interpretation and clarification of the terms used in section 1178(b) of the SSA. A few commenters recommended that the Department define, rather than clarify, these terms. Some commenters requested that the Department further clarify the terms “disease or injury,” “birth,” and “death,” to explicitly exclude information about reproductive health care. Other commenters expressed opposition to the Department’s clarifications.

Response: We decline to define “disease or injury,” “birth,” or “death” in this final rule. The Department’s understanding of these terms is consistent with the Model State Vital Statistics Act and Regulations and its application in the context of the passage of HIPAA. We believe that the 2023 Privacy Rule NPRM preamble discussion is sufficient to clarify that such reporting does not include the use or disclosure of PHI for investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating health care, including reproductive health care, or to identify a person for such activities.

Defining “Public health,” as used in the terms “public health surveillance,” “public health investigation,” and “public health intervention.”

Section 1178(b) also excepts state laws providing for “public health surveillance, or public health investigation or intervention” from HIPAA’s general preemption authority.[FN228] Neither HIPAA nor the Privacy Rule currently defines “public health surveillance” or “public health investigation or intervention.” Consistent with the statute, the Privacy Rule expressly permits a regulated entity to use or disclose PHI for “public health” surveillance, investigation, or intervention.[FN229] The Department proposed to define public health, as used in the terms “public health surveillance,” “public health investigations,” and “public health interventions,” to mean population-level activities to prevent disease and promote health of populations. In preamble to the 2023 Privacy Rule NPRM, the Department described public health surveillance as the ongoing, systematic collection, analysis, and interpretation of health-related data essential to planning, implementation, and evaluation of public health practice. [FN230] The Department explained that public health investigations or interventions include monitoring real-time health status and identifying patterns to develop strategies to address chronic diseases and injuries, as well as using real-time data to identify and respond to acute outbreaks, emergencies, and other health hazards.[FN231] Public health surveillance, investigations, or interventions safeguard the health of the community by addressing ongoing or prospective population-level issues such as the spread of communicable diseases, even where these activities involve ***33001** individual-level investigations or interventions.

The Department also proposed to expressly exclude certain activities from the definition of public health to distinguish between public health activities and certain criminal investigations. Specifically, the Department proposed to provide in regulatory text that the Privacy Rule’s permissions to use and disclose PHI for the “public health” activities of surveillance, investigations, or interventions do not include criminal, civil, or administrative investigations into, or proceedings against, any person in connection with seeking, obtaining, providing, or facilitating reproductive health care, nor do they include identifying any person for the purpose of initiating such investigations or proceedings. The Department stated that any such actions are not public health activities that would be subject to the exception to HIPAA’s general preemption authority for state laws providing for “public health surveillance, or public health investigation or intervention.” [FN232]

Commenters expressed mixed views on the proposal to define “public health” in the context of “public health surveillance,” “public health investigations” or “public health interventions.” Commenters expressing opposition to the proposal either disagreed with the Department’s assertion that public health activities do not involve uses and disclosures that would be prohibited by the rule or asserted that the proposal would prevent public health reporting of reproductive health care. Some commenters generally supported the goal of the proposal but expressed concern that inclusion of the proposed language about “population-level” activities could prevent essential public health activities that involve specific persons, such as reporting data about specific health care services provided to specific persons that have a “population-level” effect and investigating the spread of communicable diseases.

Some commenters asserted that the proposal would frustrate states’ ability to enforce their laws not related to public health, such as laws banning health care such as abortion. Supporters asserted that the proposal would help to prevent PHI from being disclosed for a purpose that would be prohibited under the proposed rule. Supportive commenters also expressed concern about states obtaining PHI based on an interpretation of “public health investigations” that includes the mandatory reporting of pregnant individuals who engage in certain activities, such as substance use. Other commenters asserted that disclosures of PHI to public health authorities should be limited because of the potential for PHI to be redisclosed for purposes that otherwise would be prohibited under the Privacy Rule.

The final rule adopts the proposed definition with some modifications. The final rule maintains the proposed rule’s focus on activities aimed at preventing disease and improving the health of populations. This definition does not prevent disclosures of PHI by covered entities to public health authorities for public health activities that have long been permitted under the Privacy Rule. As discussed in the 2023 Privacy Rule NPRM, since the time of HIPAA’s enactment, public health activities related to surveillance, investigation, or intervention have been widely understood to refer to activities aimed at improving the health of a

population. For example, legal dictionaries define “public health” as “[t]he health of the community at large,” or “[t]he healthful or sanitary condition of the general body of people or the community en masse; esp., the methods of maintaining the health of the community, as by preventive medicine or organized care for the sick.” [FN233] Stedman's Medical Dictionary defines “public health” as “the art and science of community health, concerned with statistics, epidemiology, hygiene, and the prevention and eradication of epidemic diseases; an effort organized by society to promote, protect, and restore the people's health; public health is a social institution, a service, and a practice.” [FN234] The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry have described “public health surveillance” as “the ongoing systematic collection, analysis and interpretation of outcome-specific data for use in the planning, implementation, and evaluation of public health practice.” [FN235] And many states similarly define “public health” to mean activities to support population health.[FN236] The Department likewise has used the term public health in this way since it first adopted the Privacy Rule.[FN237]

Public health surveillance, public health investigations, and public health interventions are activities that address population health concerns and have generalized public benefit [FN238] to the health of a population, including activities that involve specific persons. Examples of activities that prevent disease in and promote the health of populations include vaccination campaigns to eradicate communicable disease, surveillance of a community's use of emergency services after a natural disaster to improve allocation of resources to meet health needs, and investigation of the source of an outbreak of food poisoning. As explained in the preamble to the 2023 Privacy Rule NPRM,[FN239] there is a widely recognized distinction between public health activities, which primarily focus on improving the health of populations, and criminal investigations, which primarily focus on identifying and imposing liability on persons who have ***33002** violated the law.[FN240] States and other local governing authorities maintain criminal codes that are distinct and separate from public health reporting laws,[FN241] although some jurisdictions enforce required public health reporting through criminal statutes. Different governmental bodies are responsible for enforcing these separate codes, and public health officials do not typically investigate activities enforced under criminal statutes or laws.[FN242] Federal laws also generally treat public health investigations as distinct from criminal investigations.[FN243] Maintaining a clear distinction between public health investigations and criminal investigations serves HIPAA's broader purposes.[FN244]

The Department concludes that neither section 1178(b) nor the Privacy Rule's permissions to use and disclose PHI for the “public health” activities of surveillance, investigation, or intervention include conducting criminal, civil, or administrative investigations into, or imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care, including reproductive health care, nor do they include the identification of any person for such purposes. Such actions are not public health activities. As described above, this distinction between public health activities and other investigation and enforcement activities is not limited to reproductive health care. Public health surveillance, investigations, or interventions ensure the health of the community as a whole by addressing ongoing or prospective population-level issues such as the spread of communicable diseases, even where they involve interventions involving specific individuals. Such surveillance systems provide the necessary data to examine and potentially develop interventions to improve the public's health, such as providing education or resources to support individuals' access to health care and improve health outcomes and are not affected by this final rule.[FN245] U.S. states, territories, and Tribal governments participate in bilateral agreements with the Federal Government to share data on conditions that affect public health.[FN246] The CDC's Division of Reproductive Health collects reproductive health data in support of national and state-based population surveillance systems to assess maternal complications, mortality and pregnancy-related disparities, and the numbers and characteristics of individuals who obtain legal induced abortions.[FN247] This final rule does not affect CDC's ability to collect this information now or in the future. Importantly, disclosures to public health authorities permitted by the Privacy Rule are limited to the “minimum necessary” to accomplish the public health purpose.[FN248] In some cases, regulated entities need disclose only de-identified data [FN249] to meet the public health purpose.

By contrast, efforts to conduct criminal, civil, and administrative investigations or impose criminal, civil, and administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care generally target specific persons for particular conduct; they are not designed to address population-level health concerns and are not limited to information authorized to be collected by a public health or similar government authority for a public health activity. Thus, the

exceptions in section 1178(b) for “public health” investigations, interventions, or surveillance do not limit the Department's ability to prohibit uses or disclosures of PHI for other purposes, such as judicial and administrative proceedings or law enforcement purposes. While the Department has chosen as a policy matter to continue to permit uses or disclosures of PHI for law enforcement and other purposes in certain contexts, it is adopting a different balance where such uses or disclosures are about reproductive health care that is lawful under the circumstances in which it was provided.

While retaining the focus on activities to prevent disease and promote the health of populations, this final rule clarifies that population-level activities “include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information.” This clarification addresses commenters' concerns that regulated entities would no longer be able to report information that states need to conduct public health functions intended to protect against prospective or ongoing threats at the population level, even if at times they necessarily will focus on individuals while doing so (through contact tracing, quarantine or isolation, and the like). The Department does not intend this clarification to prevent disclosures of PHI from covered entities to public health authorities for public health activities that have long been and continue to be permitted under the Privacy Rule. These changes clarify that public health, as used in the specified terms, broadly includes activities to prevent disease in and promote the health of populations. The changes also confirm that the Department does not require a public health authority to supply an attestation to a covered entity to receive PHI of an individual where that disclosure is intended to prevent disease in or promote the health of populations.

The intended purpose of including “population-level” was to facilitate ***33003** public health activities that protect large numbers of people from epidemics, environmental hazards, and the like. However, we believe that the language that clarifies that population-level activities “include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information,” sufficiently serves this purpose of addressing uses and disclosures of PHI that are necessary to accomplish the overarching goals of public health.

The last sentence of the proposed definition, which described what are not public health activities, is also revised in the final rule for consistency with the general distinction between activities of public health surveillance, investigation, and intervention and activities of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying a person for such activities, as well as the standard the Department is adopting at [45 CFR 164.502\(a\)\(5\)\(iii\)](#), which is discussed further in that section of this rule. Thus, while a state might assert that investigating or imposing liability on persons for the mere act of seeking, obtaining, providing, or facilitating health care satisfies the definition of “public health,” their interpretation would not supersede the definition of “public health” in the context of public health surveillance, investigations, or interventions that the Department is adopting under its own Federal statutory authority to administer the HIPAA Rules.

Comment: A few organizations expressed support for the proposed definition of “public health” without further elaboration. Several commenters expressed support for the proposed definition of “public health” because it would prevent PHI from being disclosed for a prohibited purpose. A few commenters expressed support for the proposal because they believed that information reported for public health purposes could be requested, re-identified (in the case of de-identified information), or further disclosed to law enforcement for purposes for which the Department proposed to prohibit uses and disclosures.

Several commenters expressed support for the proposed definition of “public health” and the existing standard that limits public health disclosures of PHI to the minimum necessary information to achieve the purpose.

Response: Consistent with the NPRM, the Department agrees with the commenters who stated that it is important to define “public health” in the context of public health surveillance, investigation, or intervention to ensure that PHI is not disclosed for a purpose prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#). Disclosures of PHI for public health purposes continue to be subject to the minimum necessary standard, which limits the use and disclosure of PHI to the minimum necessary to achieve the specified purpose; in some circumstances, de-identified information may suffice. However, many public health activities do

require identifiable data, such as for interventions involving individuals, to protect against prospective or ongoing threats to health or safety at the population level, and the Privacy Rule does not prohibit such uses and disclosures.

When making disclosures to public officials that are permitted under [45 CFR 164.512](#), if the public official represents that the information requested is the minimum necessary for the stated purpose, regulated entities are permitted, but not required, to rely on that representation, if such reliance is reasonable under the circumstances.[FN250] Such reliance may not be reasonable where the request appears to be overly broad when compared to the stated purpose of the request (e.g., where a public health authority requests the disclosure of PHI of all individuals who received treatment for uterine bleeding when the stated purpose is to investigate infection control practices by an obstetrician/gynecologist in a state where law enforcement has publicly announced its intention to investigate individuals for traveling out of state to seek or obtain reproductive health care that is lawful under the circumstances in which it is provided).

Comment: A few commenters asserted that law enforcement generally interprets public health investigations to include criminal investigations and prosecutions and the NPRM proposed definition would complicate such investigations by limiting the amount of PHI that could be disclosed to law enforcement.

Response: The Department has adopted a definition of “public health” in the context of public health surveillance, investigation, and intervention that sets clear parameters between such activities and law enforcement activities conducted to impose liability for the mere act of seeking, obtaining, providing, or facilitating health care. Public health surveillance, investigation, and intervention do not include efforts to attach liability to persons for specific acts of seeking, obtaining, providing, or facilitating health care.

This definition is consistent with the longstanding distinction made by the Department between public health activities and law enforcement activities as described above.

Comment: Several commenters expressed support for the Department's proposal generally but recommended further clarifications or revisions to it, especially regarding the limitation to “population-level” activities. A few commenters raised questions about the difference between the proposed definition of “public health” and the permission for public health activities under [45 CFR 164.512\(b\)\(1\)\(i\)](#) and recommended that the Department clarify the definition to ensure that public health agencies are able to obtain health information for administrative or civil proceedings, such as quarantine or isolation in cases involving infectious diseases.

Response: The Department has modified the definition of “public health” in the context of public health surveillance, investigation, or intervention to clarify that such activities include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of PHI. This change addresses commenters' concerns that under the proposed definition, regulated entities would no longer be able to report PHI that is required to address population-level concerns.

Comment: Several commenters raised concerns that the proposed definition of “public health” would circumvent states' interests related to public health. A few commenters expressed opposition to the Department's clarification of public health because they believed that states should have the ability to conduct surveillance, investigations, or interventions concerning certain types of health care for public health purposes. Several commenters asserted that the proposal would frustrate the ability of states to enforce their laws prohibiting access to certain types of health care. Conversely, a commenter requested that the Department explicitly exclude reproductive health care from the proposed definition of “public health,” so it would not be reportable to public health agencies.

Response: We disagree with commenters' assertions that this final rule will prevent the reporting of vital statistics or other public health ***33004** activities. A covered entity may continue to use or disclose PHI for all the public health activities and purposes listed in section 1178(b). We also decline to explicitly exclude reproductive health care from the definition of “public health”

because doing so could hinder beneficial public health activities. Instead, this definition supports this final rule's prohibition against certain uses and disclosures of PHI by clarifying that public health surveillance, investigation, and intervention exclude conducting a criminal, civil, or administrative investigation into any person, or the imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying any person for such activities. Such excluded activities include those with the purposes that are prohibited at [45 CFR 164.502\(a\)\(5\)\(iii\)](#).

Comment: A few commenters believed that defining “investigation,” “intervention,” or “surveillance” was unnecessary or recommended against doing so and requested that the Department clarify that such terms do not encompass any prohibited purposes. One commenter requested that the Department define these terms to expressly exclude information related to reproductive health care.

Response: We are not defining the terms “investigation,” “intervention,” or “surveillance” in this rule. However, we are providing extensive interpretation in the preamble to clarify that such activities in the public health context do not encompass conducting a criminal, civil, or administrative investigation into any person, or imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying any person for such activities, including those for which use or disclosure of PHI is prohibited by [45 CFR 164.502\(a\)\(5\)\(iii\)](#).

Reporting of Child Abuse

In accordance with section 1178(b) of HIPAA, the Privacy Rule permits a regulated entity to use or disclose PHI to report known or suspected child abuse or neglect if the report is made to a public health authority or other appropriate government authority that is authorized by law to receive such reports.[FN251] The Privacy Rule limits disclosures of PHI made pursuant to this permission to the minimum necessary to make the report.[FN252]

As the Department explained in the 2023 Privacy Rule NPRM, at the time HIPAA was enacted, “most, if not all, states had laws that mandated reporting of child abuse or neglect to the appropriate authorities.” [FN253] Additionally, when Congress enacted HIPAA, it had already addressed child abuse reporting in other laws, such as the Victims of Child Abuse Act of 1990 [FN254] and the Child Abuse Prevention and Treatment Act.[FN255] For example, [34 U.S.C. 20341\(a\)\(1\)](#), a provision of the original Victims of Child Abuse Act of 1990 that is still in place today, requires certain professionals to report suspected abuse when working on Federal land or in a federally operated (or contracted) facility.[FN256] As used in these statutes, the term “child abuse” does not include activities related to reproductive health care, such as abortion.

In the 2023 Privacy Rule NPRM, the Department discussed that it has long interpreted “child abuse,” as used in the Privacy Rule and section 1178(b) of HIPAA, to exclude conduct based solely on a person seeking, obtaining, providing, or facilitating reproductive health care.[FN257] This interpretation is consistent with the public health aims of improving access to health care for individuals, including reproductive health care, and with relevant statutes at the time HIPAA was enacted, as described above. The Department also stated that this interpretation prohibits a regulated entity from disclosing PHI in reliance on the permission for reporting “child abuse” where the alleged victim does not meet the definition of “person” or “child,” consistent with both [1 U.S.C. 8](#) and section 1178(b). Additionally, consistent with previous rulemaking under HIPAA, the Department clarified in the preamble that it did not intend for the interpretation to disrupt longstanding state or Federal child abuse reporting requirements that apply to regulated entities.[FN258]

The Department also made several clarifications in preamble concerning our interpretation of section 1178(b) and the Privacy Rule's public health permission and how we distinguish between public health reporting and disclosures for law enforcement purposes or judicial and administrative proceedings.

Comment: Many commenters supported the Department's clarification and agreed that it would preserve trust between individuals and health care providers, but also requested additional clarification from the Department on its implementation. Few opposed the clarification; those who did expressed concerns about the potential for the clarification to prevent state-mandated reporting in certain circumstances. Many commenters expressed mixed views about the Department's interpretation.

Response: The Department is moving forward with its interpretation as described in the NPRM. As noted above, this final rule does not alter the Privacy Rule's reliance on other applicable law with respect to determining who has the authority to act on behalf of an individual who is an unemancipated minor in making decisions related to health care, including lawful reproductive health care.[FN259] The Privacy Rule does not permit a regulated entity to disclose PHI as part of a report of suspected child abuse based solely on the fact that a parent seeks reproductive health care (e.g., treatment for a sexually transmitted infection) for a child. However, the regulated entity is permitted to make such disclosure where there is suspicion of sexual abuse that could be the basis of permitted reporting.

Congress defined the term “child” in 1 U.S.C. 8, and the term “child” in the Privacy Rule is consistent with that definition. As such, the Department believes that to the extent this clarification prohibits a regulated entity from disclosing PHI to report “child abuse” under this permission in the Privacy Rule where the alleged victim does not meet the definition of “person,” it is consistent with both 1 U.S.C. 8 and section 1178(b).

The Department also reaffirms its clarification that the Privacy Rule permission to report known or suspected child abuse or neglect permits a disclosure only for the purpose of making a report, and the PHI disclosed must be limited to the minimum necessary information for the purpose of making a report.[FN260] These provisions do not permit the covered entity to disclose PHI in response to a request for the use or disclosure of PHI to conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on a *33005 person based on suspected child abuse. Instead, as we explained in the 2023 Privacy Rule NPRM, any disclosure of PHI in response to this type of request from an investigator, must meet the applicable Privacy Rule conditions for disclosures for judicial and administrative proceedings or law enforcement purposes, as applicable.[FN261] That is the case whether such disclosure is in follow up to the report made by the covered entity (other than to clarify the PHI provided on the report) or part of an investigation initiated based on an allegation or report made by a person other than the covered entity.[FN262]

Moreover, this clarification does not affect the ability of state authorities to invoke other permissions for disclosure under the Privacy Rule, such as the permission for disclosures for law enforcement purposes, where they are seeking PHI related to unlawful reproductive health care.[FN263] Thus, the Department's interpretation of “child abuse” continues to support the protection of children while also serving HIPAA's objectives of protecting the privacy of PHI to promote individuals' trust in the health care system and preserving the relationship between individuals and their health care providers.

Comment: A few commenters recommended that the Department expand the clarification of child abuse to broadly address providing or facilitating all health care, rather than just reproductive health care.

Response: It is beyond the scope of this rule making to expand the clarification to include the provision or facilitation of all lawful health care. We appreciate the recommendations of commenters and will take them under advisement for potential future rulemaking.

3. Adding a Definition of “Reproductive Health Care”

Section 160.103 of the HIPAA Rules defines “health care” as “care, services, or supplies related to the health of an individual.” [FN264] The definition clarifies that the term “includes but is not limited to” several identified types of care, services, and procedures [FN265] and includes examples such as therapeutic, rehabilitative, or maintenance care, as well as sale or dispensing of drugs or devices.

The Department proposed to add and define a new term, “reproductive health care,” that would be a subset of the term “health care.” [FN266] The Department proposed to define “reproductive health care” as “care, services, or supplies related to the reproductive health of the individual.” The Department noted in the NPRM preamble that the HIPAA Rules define “health care” broadly.[FN267]

Consistent with the definition of “health care” in the HIPAA Rules, the proposed definition of “reproductive health care” would have applied broadly and included not only reproductive health care and services furnished by a health care provider and supplies furnished in accordance with a prescription, but also care, services, or supplies furnished by other persons and non-prescription supplies purchased in connection with an individual's reproductive health. The Department proposed to use the term “reproductive health care” rather than “reproductive health services” to ensure that the term was interpreted broadly to capture all health care that could be furnished to address reproductive health, including the provision of medications and devices, whether prescription or over-the-counter.

The Department discussed in preamble some of the types of care, services, and supplies that were included in the proposed term. In keeping with the Department's intention for “reproductive health care” to be inclusive of all types of health care related to an individual's reproductive system, the 2023 Privacy Rule NPRM preamble indicated that the term would include, but not be limited to: contraception, including emergency contraception; pregnancy-related health care; fertility or infertility-related health care; and other types of care, services, or supplies used for the diagnosis and treatment of conditions related to the reproductive system. We also provided a non-exhaustive list of examples of health care within each of these categories of reproductive health care.

Consistent with the definition of “health care” adopted in 2000 in the HIPAA Rules, the Department did not propose a specific definition of “reproductive health” but invited comment on whether including a particular definition of “reproductive health” would be beneficial.

Many commenters supported the proposal and agreed that it would provide the necessary protections for individuals and others. Some referenced existing definitions used by other legal authorities and recommended the Department consider adopting or incorporating them in some manner.

Some commenters opposed the proposal to provide an inclusive definition of reproductive health care. Some commenters asserted that the proposal lacked clarity and was too open-ended, making it difficult to operationalize. Other commenters expressed concern that the proposed definition would permit minors to consent to reproductive health care without parental consent.

The final rule adopts the new term “reproductive health care” and definition with three modifications. First, we replace “care, services, or supplies related to the reproductive health of the individual” with “health care” and add a citation to the HIPAA Rules' definition of that term to clarify that reproductive health care is a subset of “health care.”

Second, we specify that the term means health care “that affects the health of the individual in all matters relating to the reproductive system and to its functions and processes.” In keeping with the Department's intention for “reproductive health care” to be interpreted broadly and inclusive of all types of health care related to an individual's reproductive system, this additional language clarifies that the definition encompasses the full range of health care related to an individual's reproductive health.

Third, we add a statement reaffirming that the definition should not be construed to establish a standard of care for or regulate what constitutes clinically appropriate reproductive health care.

As discussed in the NPRM, this approach is consistent with the approach the Department took when it adopted the definition of “health care” in the HIPAA Rules. At that time, the Department explained that listing specific activities would create the risk that important activities would be left out and could also create confusion.[FN268]

By describing more fully the breadth of reproductive health care, the definition may decrease the perceived burden to regulated entities of complying with the rule by helping them determine whether a request for ***33006** the use or disclosure of PHI includes PHI that is implicated by this final rule.

To further clarify what is included in reproductive health care for regulated entities, we provide a non-exclusive list of examples that fit within the definition: contraception, including emergency contraception; preconception screening and counseling; management of pregnancy and pregnancy-related conditions, including pregnancy screening, prenatal care, miscarriage management, treatment for preeclampsia, hypertension during pregnancy, gestational diabetes, molar or ectopic pregnancy, and pregnancy termination; fertility and infertility diagnosis and treatment, including assisted reproductive technology and its components [FN269] (e.g., in vitro fertilization (IVF)); diagnosis and treatment of conditions that affect the reproductive system (e.g., perimenopause, menopause, endometriosis, adenomyosis); and other types of care, services, and supplies used for the diagnosis and treatment of conditions related to the reproductive system (e.g., mammography, pregnancy-related nutrition services, postpartum care products).

Additionally, the language in the definition stating that the definition should not be construed to set forth a standard of care or regulate what constitutes clinically appropriate reproductive health care should not be read as limiting “reproductive health care” to only health care that is determined to be appropriate by a health care professional. Rather, it may be the individual who determines whether the health care they receive, such as over-the-counter contraceptives, is appropriate. Like the definition of “health care,” the definition of reproductive health care is intended to be broad. Finally, we clarify that meeting the definition is not sufficient for information about such health care to be protected under the HIPAA Rules or this final rule. Rather, the information about such health care still needs to meet the definition of PHI.[FN270]

Comment: Some commenters expressed support for the proposed definition of “reproductive health care.” Several commenters specifically expressed their support for a broad definition of the term for various reasons, including: ensuring that providers of reproductive health care can continue to serve vulnerable communities and reduce health care disparities; providing clarity; and mitigating the need for clinical expertise and interpretation for each request for reproductive health information. Other commenters expressed support for the term because it would improve access to care and better reflect the breadth of services that support an individual's reproductive health, enable health care providers to continue to maintain appropriate data safeguards, and enable individuals to feel comfortable disclosing their information without fear of incrimination.

Many other commenters expressed opposition to the proposed definition because it was too expansive and would encompass procedures that they did not consider to be reproductive health care. Many commenters explicitly requested that the definition exclude certain types of health care. A few commenters recommended that the Department narrow the proposed definition to apply only to records directly involving certain specified services and clarify that the final definition does not include other procedures or treatments related to pregnancy or contraception. Another commenter expressed opposition to the proposed definition of “reproductive health care” because they believe that reproductive health information is no more sensitive than other medical information and should not be treated differently.

One commenter opposed the proposed definition of “reproductive health care” because they thought it would prevent health care providers from disclosing PHI to other health care providers for treatment, which would erode individual trust.

Several commenters requested that the Department expand the proposed definition, be more specific in its meaning (e.g., provide additional information about the types of care, services, or supplies included in the definition), or replace it with a more expansive term (e.g., “sensitive personal health care” meaning “care, services, or supplies related to the health of the individual which could expose any person to civil or criminal liability for the mere act of seeking, obtaining, providing, or facilitating such health care”). A commenter urged the Department to define the term “sexual and reproductive health care” to ensure that individuals have reproductive health care privacy, regardless of their sexual orientation or gender identity.

Commenters offered several alternative definitions or terms, such as “including but not limited to services related to contraception, sterilization, preconception care, maternity care, abortion care, and counseling regarding reproductive health care”; the definition of “reproductive health care services” at 18 U.S.C. 248(e)(5); “reproductive and sexual health care services” as defined in [California Health and Safety Code section 1367.31](#); and limiting the definition to capture only health care that

is at risk of being investigated or prosecuted because of Dobbs. Other commenters requested additional precision or clarity in the definition. For example, a commenter recommended that the definition include the specific codes and data points that would constitute reproductive health care that would be prohibited from disclosure under the proposed rule (e.g., International Classification of Diseases (ICD) codes related to reproductive health, ABO blood type and Rh factor).

Several commenters urged the Department to narrow the proposed definition because of operational concerns, including the redirection of resources to making or obtaining legal determinations about whether a particular type of care was reproductive health care. Some explained that health information management staff generally do not have the clinical expertise to determine what would constitute “reproductive health care,” while another stated that physicians would also have trouble discerning what health care would meet the proposed definition. Another commenter recommended that the Department include only PHI that is already reliably segregated in EHRs in the definition.

Many commenters requested that the Department further explain the proposed definition either in preamble or the regulatory text. One commenter suggested that in lieu of a definition of “reproductive health care,” the Department include an extensive discussion of examples in the preamble and provide entities flexibility to implement policies or procedures that may be affected by the definition of “reproductive health care” in accordance with their operational structures. A few commenters also recommended that the Department provide examples in preamble discussion, rather than regulatory text. One commenter recommended that the Department provide specific examples to illustrate its meaning where there could be ambiguity. Several commenters recommended that examples be included in the regulatory text and provided specific examples of the types *33007 of health care they thought should be included. Some commenters recommended the Department include examples but did not specify whether they should be in the preamble or in the regulatory text, while other commenters requested that the Department include a non-exhaustive list of examples of reproductive health care in both the regulation and preamble.

Response: After consideration, we have finalized a definition grounded in the Privacy Rule's long-established term “health care.” We provide a non-exhaustive list of examples in preamble above. We do not explicitly address all of the many types of health care suggested in comments to avoid creating the impression of a complete list. This is also consistent with our approach regarding the definition of “health care.” We emphasize that this definition does not set or affect standards of care, nor does it affect uses and disclosures of PHI for treatment purposes. Operational concerns expressed by some commenters are addressed in response to comments on the prohibition.

4. Whether the Department Should Define Any Additional Terms

The Department requested comments about whether it would be helpful for the Department to define “reproductive health” or any additional terms.[FN271]

Comment: Several commenters recommended that the Department define “reproductive health” because it would ensure that all covered entities would be required to implement changes, or that the PHI of individuals receiving certain types of health care would not be disclosed to states where individuals who receive such health care is being penalized.

Several commenters urged the Department to add the definition of reproductive health adopted by the United Nations and World Health Organization, while others recommended the adoption of the definition articulated by the International Conference on Population and Development in 1994. One commenter expressed opposition to adding a definition of reproductive health as unnecessary, and another instead recommended adoption of a precise definition of “reproductive health care.”

Another commenter recommended expanding the definition of PHI to include certain digital data of entities not regulated under HIPAA (e.g., information from period tracking apps). One commenter recommended revising the definition of “health oversight agency” to exclude agencies that investigate or prosecute activities related to reproductive health care. Some commenters requested that the Department define additional terms or clarify existing terms.

Rather than define additional terms, one commenter recommended that the Department ensure that all the proposed definitions would be aligned with the Office of the National Coordinator for Health Information Technology (ONC) and CMS-mandated data elements for Certified Electronic Health Record Technology products and in the electronic clinical quality measures that health care providers are required to report to CMS.

Response: We appreciate the feedback from commenters, but upon further consideration, have concluded that defining any of the additional terms or clarifying additional existing ones is not necessary to support the implementation of this final rule. We also clarify that because HIPAA only authorizes the Department to protect IIHI used or disclosed by covered entities and their business associates, we are not able to regulate information that individuals themselves store and share using consumer health apps.

B. Section 164.502—Uses and Disclosures of Protected Health Information: General Rules

Section 164.502 of the Privacy Rule contains the general rules governing uses and disclosures of PHI. Paragraph (a)(1) of this section sets forth the list of permitted uses and disclosures.

1. Clarifying When PHI May Be Used or Disclosed by Regulated Entities

Section 164.502(a)(1)(iv) generally permits a regulated entity to use or disclose PHI pursuant to and in compliance with a valid authorization under 45 CFR 164.508, except for uses and disclosures of genetic information by a health plan for underwriting purposes prohibited under 45 CFR 164.502(a)(5)(i). Thus, an authorization that purports to allow a health plan to use or disclose PHI for that prohibited purpose is not valid under the Privacy Rule.

The Department proposed to modify 45 CFR 164.502(a)(1)(iv) to incorporate an additional limitation on the ability of a regulated entity to use and disclose PHI pursuant to an individual's authorization.[FN272] Specifically, the Department's proposal would prohibit a regulated entity from using or disclosing PHI pursuant to an individual's authorization where the purpose of the disclosure is for a criminal, civil, or administrative investigation or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided, or to identify any person for the purpose of initiating such activities. As explained in the 2023 Privacy Rule NPRM, the proposed modification was intended to prevent the misuse of the general permission for a regulated entity to use or disclose PHI pursuant to an individual's authorization to bypass the proposed prohibition against using and disclosing PHI for purposes that would be prohibited by proposed 45 CFR 164.502(a)(5)(iii).

The Department explained in the proposed rule that this change to the authorization permission was necessary to protect individuals' privacy by precluding any possibility that a third party, such as a law enforcement official, could coerce or attempt to coerce an individual into signing an authorization, thereby enabling the third party to circumvent the prohibition proposed at 45 CFR 164.502(a)(5)(iii).

The Department also proposed to modify the general rules in 45 CFR 164.502(a)(1)(vi) to expressly condition certain uses and disclosures made under 45 CFR 164.512 on the receipt of an attestation pursuant to proposed 45 CFR 164.509, which is discussed below in greater detail. For clarity, the Department proposed to revise 45 CFR 164.502(a)(1)(vi) by replacing the sentence containing the conditions for certain permitted uses and disclosures with a lettered list.

Public comments about the use of authorization to use and disclose PHI for the purposes the Department proposed to prohibit in the 2023 Privacy Rule NPRM were generally divided between opposing views and supportive views, although only a few comments expressed full support for the proposal, as drafted. While many commenters shared the Department's concerns about the potential for individuals to be coerced into providing an authorization, some of these commenters nonetheless opposed the proposal because it could limit beneficial disclosures, cause uncertainty about the validity of an authorization, increase the burden on regulated entities, or seem to conflict with state laws that permit the disclosure of certain health information with the individual's explicit written consent.

The Department received no comments on its proposal to replace the ***33008** sentence at [45 CFR 164.502\(a\)\(1\)\(vi\)](#) with a lettered list. Comments on the Department's proposal to condition certain disclosures made under [45 CFR 164.512](#) on the receipt of an attestation as required by proposed [45 CFR 164.509](#) are discussed below in greater detail.

The Department is not finalizing its proposal to prohibit a regulated entity from using or disclosing an individual's PHI for the specified purposes pursuant to and in compliance with an individual's authorization. We agree with the majority of public comments discussed in detail below that generally expressed the view that the Privacy Rule's authorization requirements empower individuals to make decisions about who has access to their PHI. We acknowledge that maintaining the permission for regulated entities to obtain an individual's authorization to use and disclose PHI could leave an individual exposed to the potential for duress or coercion by a third party. It could also expose a health care provider or other person who provides or facilitates reproductive health care to liability in the event the authorization is used to affect a disclosure for a prohibited purpose in connection with lawful reproductive health care. However, we believe that continuing to permit uses and disclosures pursuant to an individual's authorization best preserves individual autonomy concerning uses and disclosures of their PHI. Consistent with our practice described above, the Department will monitor closely the interaction of the revised Privacy Rule and the evolving legal landscape to ensure an appropriate balance of protecting the privacy interests of individuals and permitting access to PHI for non-health care purposes.

As we discussed in the proposed rule, there is a relationship between the provision allowing an individual to authorize a regulated entity to use or disclose the individual's PHI to a third party and the HITECH Act requirement that a regulated entity comply with an individual's direction to transmit to another person an electronic copy of the individual's PHI in an EHR ("individual access right to direct").[FN273] Both enhance an individual's autonomy by providing them with the ability to determine who can access the individual's PHI as specified in the authorization or access request. Both also create an opportunity for coercion or attempted coercion of an individual by another person (e.g., a law enforcement official could attempt to coerce an individual into providing the law enforcement official with access to the individual's PHI by offering the individual a reduced sentence for an alleged crime). And while we remain concerned about the potential for coercion or attempted coercion, even if the Department were to finalize the proposed limitation on uses and disclosures with an authorization, the individual would retain the individual access right to direct, which is enshrined in statute. We also believe it would be inconsistent with the spirit of individual access right to direct for the Department to limit the ability of an individual to authorize a regulated entity to disclose their PHI to another person.

For the foregoing reasons, we are not finalizing this proposal, and the language in [45 CFR 164.502\(a\)\(1\)\(iv\)](#) remains unchanged.

Comment: While some commenters expressed concern about the potential for coercion described in the proposed rule, they did not all agree that it would be appropriate to address this concern by prohibiting such disclosures pursuant to an authorization. Some commenters asserted that coercion concerns would not be eliminated by curtailing the ability of individuals to authorize disclosures of their PHI in certain circumstances.

Some commenters explained that prohibiting individuals from requesting disclosures of their PHI pursuant to an authorization for prohibited purposes would create a significant burden for regulated entities, primarily because of the frequent failure of persons requesting the use or disclosure of PHI to provide sufficient detail regarding the purpose of the request to allow them to determine if it would be for a prohibited purpose.

A few commenters asserted that a HIPAA authorization is the safest approach to ensuring an individual is aware of and agrees to the use or disclosure of their PHI. One of those commenters recommended that the Department permit a regulated entity to disclose PHI pursuant to a valid authorization unless the covered entity has actual knowledge that an authorization was not voluntary. A commenter recommended adding a disclaimer or warning to the authorization to provide assurances that an individual was not coerced into disclosing their PHI to law enforcement or other third party that might seek to use the PHI for improper purposes. Still another commenter recommended that the Department require the authorization to indicate the types

of sensitive information the individual intends to share. One commenter recommended that certain disclosures be accompanied by a notice of the individual's rights under the Privacy Rule.

Response: We appreciate comments concerning this proposal and the restriction of individuals' ability to maintain control over their PHI by prohibiting the use of written authorization. The Privacy Rule's written authorization requirements are the most objective means by which an individual can provide direction to a regulated entity about the use and disclosure of their PHI known to a regulated entity. The right of individuals to access their PHI and choose to disclose their PHI to another person is a cornerstone of HIPAA, and as such, we are not proceeding with this proposal. The Department will continue to monitor complaints we receive and the outcome of enforcement actions to identify potential coercion and the effect of permitting individuals to authorize the disclosure of PHI for purposes that are prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#) on the relationship between health care providers and individuals.

We also appreciate the comments that asserted that restricting the ability of regulated entities to use an authorization to obtain PHI for the purposes prohibited in this rulemaking could create a burden for the regulated entities.

To the extent that individuals wish to authorize the use and disclosure of their PHI, particularly when a request is not clear, or when a request seeks only partial parts of a record, a written authorization provides the regulated entity with the opportunity to clarify, with both the individual and the person requesting the disclosure, the PHI that will be disclosed. State laws that require regulated entities to obtain an individual's written consent are generally considered more privacy protective, and thus are not preempted.

Comment: Several commenters expressed support for eliminating the ability of regulated entities to use or disclose PHI pursuant to an authorization in certain circumstances because of the potential for harm to individuals as proposed. One commenter described the potential negative effects of permitting uses and disclosures pursuant to an authorization in certain circumstances on individuals from historically marginalized communities. Another commenter asserted that individuals frequently do not read consent forms provided to them for signature for a variety of reasons, including proficiency. Some commenters expressed concerns that individuals who are the subject of a ***33009** criminal investigation or prosecution would be placed in situations where it would not be possible to obtain a voluntary authorization (e.g., a custodial situation), or that law enforcement could seek to persuade an individual to provide them with access to the individual's PHI through improper means.

Response: We continue to share the concern expressed by commenters about the potential for coercion or harassment of individuals, particularly those in marginalized or underserved communities, to provide authorization for the use or disclosure of their PHI. According to many reports and data cited by the Department and commenters, such individuals more often experience negative interactions with law enforcement or other prosecutorial authorities. We urge HIPAA regulated entities to be mindful of Privacy Rule requirements that could help mitigate the potential for harm resulting from coercion or difficulties individuals may experience in understanding an authorization. For example, [45 CFR 164.508\(b\)\(2\)\(v\)](#) holds invalid authorizations that include "material information [. . .] known by the covered entity to be false"; [45 CFR 164.508\(c\)\(1\)\(iv\)](#) requires that every authorization include a description of each purpose of the requested use or disclosure; and [45 CFR 164.508\(c\)\(3\)](#), requires the authorization be written in plain language.[FN274] The Department will continue to monitor complaints, questions, and enforcement outcomes for potential harm from disclosures resulting from authorizations.

Comment: A few commenters requested clarifications of how the proposal would affect other disclosures made pursuant to the Privacy Rule, including disclosures to the individual's attorney, and whether the Department intended it to apply to other consumer-initiated requests, such as part of an Application Programming Interface (API).

A commenter recommended that health care providers be permitted to refuse to release PHI to any consumer health app when the information could lead to civil or criminal repercussions for the health care provider unless the app developer signs a binding agreement that protects them.

Response: We are not finalizing the proposal, but state here that the Department did not intend to affect or disrupt the ability of covered entities to make other disclosures of PHI pursuant to a written authorization under the Privacy Rule. Additionally, as discussed above, individuals have the right to obtain a copy of their PHI and the individual access right to direct, which could involve releasing PHI to a consumer health app or an API. With respect to EHR and technology vendors and other third parties who facilitate the exchange of PHI on behalf of covered entities, we continue to stress that valid business associate agreements are required by the Privacy Rule and necessary to protect the privacy of the individuals who are the subject of the PHI. ONC also has made clear that it intends to advance technologies that support requirements already extant under the HIPAA Privacy Rule. [FN275] Additionally, the Department continues to urge covered entities that have direct contact with individuals to educate such individuals on the risks of disclosing their PHI to persons that are not regulated by HIPAA.[FN276] We will continue to ensure that regulated entities enter into business associate agreements as required by the Privacy Rule.[FN277] We will continue to monitor complaints, questions, and enforcement outcomes.

Comment: Many commenters addressed the relationship between the Department's proposal to eliminate the option for an individual to request disclosure of their information for the prohibited purposes pursuant to an authorization and the individual right of access, particularly, the right of an individual to direct a regulated entity to transmit to a third party an electronic copy of their PHI in an EHR. Several commenters recommended that the Department curtail the individual access right to direct. Some commenters expressed concern about the potential for individuals to be coerced into providing access to their PHI to third parties. A few commenters expressed concerns that some third parties sell PHI for purposes adverse to individuals' interests, including some of the purposes described in the 2023 Privacy Rule NPRM.

A few commenters provided recommendations for ways to educate individuals regarding their rights under the Privacy Rule.

Response: Although we appreciate the comments on this topic, any modifications to the individual access right to direct are beyond the scope of this rulemaking. We reiterate here that covered entities and their technology vendors that meet the definition of business associates must ensure that valid business associate agreements are in place,[FN278] and we urge them to facilitate individuals' awareness of the risks of using third-party consumer apps that are not regulated by HIPAA.[FN279] The Department continues to appreciate the identification of better education resources for individuals and health care providers and commits to providing educational resources through its website, regional offices, and webinars.

2. Adding a New Category of Prohibited Uses and Disclosures

Generally, the Privacy Rule prohibits the use or disclosure of PHI except as permitted or required by the Privacy Rule. [Paragraph \(a\)\(5\) of section 164.502](#) contains specific purposes for which the Privacy Rule explicitly prohibits the use and disclosure of PHI. [Section 164.502\(a\)\(5\)\(i\)](#) prohibits most health plans from using or disclosing PHI that is genetic information for underwriting purposes, while [45 CFR 164.502\(a\)\(5\)\(ii\)](#) prohibits a regulated entity from selling PHI, except when they have obtained a valid authorization from the individual who is the subject of the PHI.

The Department proposed to add a new paragraph, [45 CFR 164.502\(a\)\(5\)\(iii\)](#), to prohibit regulated entities from using or disclosing an individual's PHI for certain additional purposes, and to describe the scope, applicability, and limitations of the prohibition. Similar to most other ***33010** prohibitions within the Privacy Rule, this prohibition would be purpose-based, rather than a blanket prohibition against uses and disclosures of certain types of PHI.[FN280] The Department's rationale for this approach was four-fold: (1) to be consistent with the existing Privacy Rule permissible use and disclosure structure with which regulated entities are familiar, including the permission to disclose to law enforcement for certain purposes; (2) to avoid imposing a requirement on regulated entities that would necessitate the adoption and implementation of costly technology upgrades to enable data segmentation; [FN281] (3) to recognize that PHI about an individual's reproductive health care may be used or disclosed for a wide variety of purposes, and permitting the use or disclosure of PHI for some of those purposes would erode individuals' ability to trust in the health care system; and (4) to avoid any misperception that the Department is setting a standard of care or substituting its judgment for that of individuals and licensed health care professionals.

Proposed 45 CFR 164.502(a)(5)(iii)(A) would establish a new prohibition against the use or disclosure of PHI. Section (a)(5)(iii)(A)(1) would prohibit the use or disclosure of PHI where the use or disclosure is for a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care. Section 164.502(a)(5)(iii)(A)(2) would prohibit the use or disclosure of PHI to identify any person for the purpose of initiating a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care.

The Department proposed 45 CFR 164.502(a)(5)(iii)(B) to explain that “seeking, obtaining, providing, or facilitating” would include, but not be limited to, expressing interest in, inducing, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, assisting, or otherwise taking action to engage in reproductive health care; or attempting any of the same. As the Department explained in the 2023 Privacy Rule NPRM, the proposed prohibition would apply to any request for PHI to facilitate a criminal, civil, or administrative investigation or proceeding against any person, or to identify any person to initiate an investigation or proceeding, where the basis for the investigation, proceeding, or identification is that the person sought, obtained, provided, or facilitated reproductive health care that is lawful under the circumstances in which such health care is provided. The Department further explained that, consistent with its HIPAA authority, the prohibition would preempt state or other laws requiring a regulated entity to use or disclose PHI in response to a court order or other type of legal process for a purpose prohibited under the proposed rule. Conversely, the prohibition would not preempt laws that require the use or disclosure of PHI for other purposes, such as: public health activities; [FN282] investigations of sexual assault committed against an individual where such use or disclosure is conditioned upon the receipt of an attestation; or investigations into human and sex trafficking, child abuse, or professional misconduct or licensing inquiries.[FN283]

The Department also proposed to subject this prohibition to a Rule of Applicability in 45 CFR 164.502(a)(5)(iii)(C). As the Department explained, the proposed prohibition in 45 CFR 164.502(a)(5)(iii) would prohibit a regulated entity from using or disclosing PHI for certain purposes against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care that is “lawful under the circumstances in which such health care is provided.” [FN284] The Department further explained that it proposed a framework for regulated entities to determine whether the reproductive health care at issue was lawful under the circumstances in which such health care was provided. The proposed language of the Rule of Applicability under this rule would apply where one or more of three specified conditions exist.

The first condition, as proposed in 45 CFR 164.502(a)(5)(iii)(C)(1), addressed reproductive health care provided outside of the state that authorized the investigation or proceeding where such health care is lawful in the state where it is provided. In the proposed rule, we also clarified that the proposal would apply the prohibition in a situation in which the health care is ongoing, has been completed, or has not yet been obtained, provided, or facilitated. The proposed prohibition would recognize that any interest of society in conducting an investigation or proceeding against a person would require balancing with, and generally be outweighed by, the interests of society in protecting the privacy interests of individuals when they access lawful health care. As discussed above, privacy interests are heightened with respect to reproductive health care that is lawful under the circumstances in which it is provided as compared to the interests of law enforcement, and private parties afforded legal rights of action, in investigating or imposing liability for actions related to lawful reproductive health care.

The second condition, proposed in 45 CFR 164.502(a)(5)(iii)(C)(2), addressed reproductive health care protected, required, or authorized by Federal law, regardless of the state in which such health care is provided. It would apply the prohibition to reproductive health care that is lawful under the applicable Federal law and where the investigation or proceeding is against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care. It would apply, for example, where the underlying reproductive health care continues to be protected by the Constitution, such as contraception, or is expressly required or authorized under Federal law.[FN285]

The third condition, proposed in 45 CFR 164.502(a)(5)(iii)(C)(3), would apply the prohibition when the relevant criminal, civil, or administrative investigation or proceeding is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care that is provided in a state consistent with and permitted by the law of that same state.

The Department also proposed a Rule of Construction in 45 CFR 164.502(a)(5)(iii)(D) that provided that the proposed prohibition should not be construed to prohibit a use or disclosure of PHI otherwise permitted by the Privacy Rule unless such use or disclosure is primarily for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.[FN286] The Department proposed the Rule of Construction to avoid an erroneous interpretation of the prohibition *33011 standard, which otherwise could have been construed to prevent regulated entities from using or disclosing PHI for the purpose of defending themselves or others against allegations that they sought, obtained, provided, or facilitated reproductive health care that was not lawful under the circumstances in which it was provided.

Most of the comments addressing the proposed prohibition expressed support for the Department's purpose-based approach and the principle that the Privacy Rule should prohibit the use and disclosure of PHI for a criminal, civil, or administrative investigation into or proceeding against any person, or to identify any person to initiate a criminal, civil, or administrative investigation into or proceeding against any person, in connection with seeking, obtaining, providing, or facilitating lawful reproductive health care. At the same time, the Department received many comments that expressed concern about the proposal's clarity and regulated entities' ability to operationalize the Rule of Applicability and Rule of Construction. For example, commenters asserted that to the extent the proposed rule would require regulated entities to determine whether the requested PHI was about reproductive health care that was lawful under the circumstances in which it was provided, making such a determination could be unduly burdensome when the request was about reproductive health care that was not provided by the regulated entity that received the request and could expose them to legal risk in the absence of additional guidance or a safe harbor. Other commenters expressed concern that applying the prohibition would undermine the ability of states to enforce their own health care laws.

Commenters who addressed the proposed Rule of Construction also expressed confusion about how the Department intended “primarily” or “primarily for the purpose of” to be interpreted. Many either requested examples of uses and disclosures that were “primarily” for the underlying prohibited purposes. In lieu of the proposal to avoid liability based on “the mere act of” seeking, obtaining, providing, or facilitating reproductive health care, a few commenters suggested expanding the proposed definition or modifying existing permissions to explicitly exclude conduct based solely on seeking, obtaining, providing, or facilitating certain types of health care.

The Department is finalizing the proposed prohibition that restricts the ability of regulated entities to use or disclose PHI for activities with the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it was provided, or to identify any person for such purposes, with modifications to improve clarity and ease implementation for regulated entities.

The Department is retaining its purpose-based approach in the final rule in light of concerns about the ability of regulated entities to segment certain types of data and in recognition that PHI about an individual's reproductive health may be reflected throughout an individual's longitudinal health record, in addition to being maintained by a wide variety of regulated entities.

As we discussed in the 2023 Privacy Rule NPRM, the Department recognizes that diseases and conditions that are not directly related to an individual's reproductive health may be affected by or have bearing on the individual's reproductive health and the reproductive health care they are eligible to receive, and vice versa. Thus, it may be necessary for all types of health care providers to maintain complete and accurate medical records to ensure that subsequent health care providers are adequately informed in making diagnoses or recommending courses of treatment. For example, an individual with a chronic cardiac or endocrine condition may become pregnant, placing additional strain on the individual's cardiovascular or endocrine system. In such cases, it is essential that their cardiologist or endocrinologist be informed of the pregnancy and consulted as necessary to ensure appropriate health care is provided to the individual because such conditions may have bearing on their pregnancy.

Additionally, the final rule revises the prohibition standard at 45 CFR 164.502(a)(5)(iii) by incorporating language from the proposed Rule of Construction to clarify the purposes for which the Department prohibits uses or disclosures of PHI. In 45 CFR 164.502(a)(5)(iii)(A)(1) and (2), the Department incorporates the “mere act of” language of the proposed Rule of Construction to clarify that the prohibited uses and disclosures of PHI are tied to imposing criminal, civil, or administrative liability for the “mere act of” seeking, obtaining, providing, or facilitating reproductive care and not just “in connection to” such acts.[FN287] Section 164.502(a)(5)(iii)(A)(1) combines the criminal, civil, or administrative investigations language from the proposed prohibition standard with the proposed Rule of Construction to prohibit regulated entities from using or disclosing PHI for activities conducted for the purpose of a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care. Section 164.502(a)(5)(iii)(A)(2) separates and replaces the “or proceeding against” language from the first condition of the proposed prohibition standard with “to impose criminal, civil, or administrative liability on” and incorporates language from the proposed Rule of Construction to prohibit regulated entities from using or disclosing PHI for activities conducted for the purpose of imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care. Similar to proposed 45 CFR 164.502(a)(5)(iii)(A)(2), 45 CFR 164.502(a)(5)(iii)(A)(3) now addresses the use or disclosure of PHI to identify any person for the activities described in the other conditions of the prohibition standard. To the extent the purpose in 45 CFR 164.502(a)(5)(iii)(A)(1) relates to activities conducted for an investigation, the purpose in 45 CFR 164.502(a)(5)(iii)(A)(2) relates to the activities to impose liability, including activities that would flow from that investigation, whether it be in the form of proceedings to consider censure, medical license revocation, the imposition of fines or other penalties, or detainment or imprisonment, or the actual imposition of such liability.

The prohibition against the uses and disclosures of PHI finalized in 45 CFR 164.502(a)(5)(iii)(A) is subject to the Rule of Applicability that the Department is finalizing in 45 CFR 164.502(a)(5)(iii)(B). As discussed in the proposed rule and finalized herein, the Rule of Applicability modifies the prohibition standard to make clear that the prohibition encompasses the use or disclosure of PHI for any activities conducted for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that the regulated entity that has received the request for PHI has reasonably determined is lawful under the circumstances in which such health care is provided. The prohibition's ***33012** reference to the “mere act” of seeking, obtaining, providing, or facilitating lawful reproductive health care includes the reasons that the reproductive health care was sought or provided (e.g., an investigation into whether a particular abortion was necessary to save a pregnant person's life would constitute an investigation into the “mere act” of seeking, obtaining, providing, or facilitating reproductive health care). The reference to “mere act” operates the same way with respect to activities conducted to identify any individual for the purposes described above. This includes but is not limited to law enforcement investigations, third party investigations in furtherance of civil proceedings, state licensure proceedings, criminal prosecutions, and family law proceedings. Examples of criminal, civil, or administrative investigations or activities to impose liability for which regulated entities would be prohibited from using or disclosing PHI would also include a civil suit brought by a person exercising a private right of action provided for under state law against an individual or health care provider who obtained, provided, or facilitated a lawful abortion, or a law enforcement investigation into a health care provider for lawfully providing or facilitating the disposal of an embryo at the direction of the individual.

The Department acknowledges that this final rule will not prohibit the use or disclosure of PHI in all instances in which persons request the use or disclosure of PHI for an investigation or to impose liability on a person for seeking, obtaining, providing, or facilitating reproductive health care. As discussed extensively in Section III of this rule, the Privacy Rule has long balanced the privacy interests of individuals with that of society in obtaining PHI for certain non-health care purposes. Accordingly, we acknowledge that in some circumstances, an individual's privacy interest in obtaining lawful care will outweigh law enforcement's interests in the PHI for certain non-health care purposes, while in others, law enforcement's interests in the PHI will outweigh the privacy interests of individuals. As we discussed above in Section III and in the proposed rule, recent developments in the legal landscape have made information about an individual's reproductive health more likely to be sought for punitive non-health care purposes, such as targeting individuals for seeking lawful reproductive health care outside of their home state, and therefore more likely to be subject to disclosure by regulated entities if the requested disclosure is permitted under the Privacy Rule. The Department's approach in this rulemaking limits the application of the prohibition to situations in

which reproductive health care meets one of the conditions of the Rule of Applicability. Accordingly, the prohibition applies only where individuals' privacy interests outweigh the interests of law enforcement, and private parties afforded legal rights of action, in obtaining individuals' PHI for the non-health care purpose of investigating or imposing liability for reproductive health care that was not lawful under the circumstances in which it was provided.

We also acknowledge, as we did in the proposed rule, that in some circumstances, the Privacy Rule imposes greater restrictions on uses and disclosures of PHI than state privacy laws, and the prohibition may delay or hamper enforcement of certain other state laws (e.g., laws governing access to reproductive health care). Such circumstances were contemplated by Congress when it enacted HIPAA.[FN288] For example, a state law might require a covered entity to disclose PHI to law enforcement in furtherance of an investigation, while the final rule may prohibit such a disclosure. In such cases, the provisions of the Privacy Rule would preempt the application of contrary provisions of state law, and the regulated entity could not disclose the PHI.[FN289] However, as discussed above in section III, we reiterate that not all methods to investigate the lawfulness of reproductive health care are foreclosed by this rule.

The Department emphasizes that the prohibition does not apply in circumstances that fall outside of its terms. Where a person requesting PHI identifies a legal basis for the request beyond the mere act of a person having sought, obtained, provided, or facilitated reproductive health care that was lawful under the circumstances in which it was provided, the prohibition at [45 CFR 164.502\(a\)\(5\)\(iii\)](#) would not apply. Similarly, if a person obtains reproductive health care that was unlawful, such health care would not be lawful under the circumstances in which it was provided, and the prohibition would not apply. Where the prohibition does not apply, the Privacy Rule permits the requested PHI to be used or disclosed, provided that the use or disclosure is otherwise permitted by the Privacy Rule (i.e., the request meets the requirements of an applicable permission and is accompanied by a valid attestation as described by [45 CFR 164.509](#), where required). The Department reminds the public that persons who request PHI under false pretenses may be subject to criminal penalties under HIPAA.[FN290]

The Rule of Applicability, as discussed below, vests the determination of whether the reproductive health care was lawful under the circumstances it was provided with the regulated entity that receives the request for PHI and requires that such determination be reasonable. The regulatory presumption, also discussed below, replaces the proposed requirement that a regulated entity make a determination regarding the lawfulness of the reproductive health care where someone other than the regulated entity that receives the request provided such health care. The new language requires that the reproductive health care at issue be presumed lawful under the circumstances in which such health care is provided when provided by a person other than the regulated entity receiving the request. This helps to ensure that the regulated entity is not required to make a determination about the lawfulness of such health care. The presumption may be overcome if certain conditions are met.

In the proposed rule, the Department provided examples that remain helpful in illustrating the operation of the clarified prohibition and how it continues to permit uses and disclosures for legitimate interests.[FN291] For example, the prohibition does not restrict a regulated entity from using or disclosing PHI to a health oversight agency conducting health oversight activities, such as investigating whether reproductive health care was actually provided or appropriately billed in connection with a claim for such services, or investigating substandard medical care or patient abuse.[FN292] However, as discussed above, investigating substandard medical care ***33013** or patient abuse may not be used as a pretext for investigating reproductive health care for purposes that are otherwise prohibited by this final rule. In another example, the rule does not bar a regulated entity from using or disclosing PHI to investigate an alleged violation of the Federal False Claims Act or a state equivalent based on unusual prescribing or billing patterns for erectile dysfunction medication.

This final rule also does not prohibit the use or disclosure of PHI where the PHI is sought to investigate or impose liability on a person for submitting a false claim for reproductive health care for payment to the government. In such a case, the request is not made for the purpose of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care. Instead, the purpose of the request for PHI is to investigate or impose liability on a person for an alleged violation of the Federal False Claims Act or a state equivalent.[FN293] As another example, the revised prohibition standard generally does not prohibit the disclosure of PHI to an Inspector General where the PHI is sought to conduct

an audit aimed at protecting the integrity of the Medicare or Medicaid Program where the audit is not inconsistent with this final rule. This is because the request is generally not being made for the purpose of investigating or imposing liability on a person for the mere act of providing the reproductive health care itself. The prohibition also makes clear that the use or disclosure of PHI is permitted where the purpose of the use or disclosure is to investigate alleged violations of Federal nondiscrimination laws or abusive conduct, such as sexual assault, that may occur in connection with reproductive health care. The prohibition likewise makes clear that the use or disclosure of PHI is permitted where the purpose of the use or disclosure is to penalize the provision of reproductive health care that is not lawful, as defined by the Rule of Applicability at [45 CFR 164.502\(a\)\(5\)\(iii\)\(B\)](#), as long as a Privacy Rule permission applies.

Under the prohibition, a regulated entity could respond to a request for relevant records in a criminal or civil investigation pursuant to [18 U.S.C. 248](#) regarding freedom of access to clinic entrances. Investigations under this provision are conducted for the purpose of determining whether a person physically obstructed, intimidated, or interfered with persons providing “reproductive health services,” [FN294] or attempted to do so. Thus, they do not involve investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that was reasonably determined to be lawful under the circumstances in which such health care was provided by the regulated entity that received the request for PHI.

The final rule retains the proposal's prohibition against the use or disclosure of PHI for activities conducted for the purpose of investigating or imposing liability on “any person” for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided, or for identifying “any person” for such activities. “Any person” means, based on the HIPAA Rules' definition of “person,” [FN295] that the prohibition is not limited to use or disclosure of PHI for use against the individual; rather, the prohibition applies to the use or disclosure of PHI against a regulated entity, or any other person, including an individual or entity, who may have obtained, provided, or facilitated lawful reproductive health care.[FN296]

The Department has always and continues to recognize that there may be a public interest and benefit in disclosing PHI for limited non-health care purposes, including enforcing duly enacted laws. The Department has also always sought to balance competing interests in individual privacy and the use and disclosure of PHI for particular purposes in the Privacy Rule. We balance these competing interests by considering both the harm to individuals that results from the use or disclosure of PHI (e.g., loss of trust in the health care system, potential for financial liability or detainment) and the countervailing interests in disclosure. As discussed above, the Department finds that the final rule reflects the appropriate balance between these interests by prohibiting the use and disclosure of PHI for activities conducted for the purpose of investigating or imposing liability on “any person” for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided, or for identifying “any person” for such activities.

Accordingly, the final rule adopts, with modifications discussed below, the proposed Rule of Applicability and re-designates it as [45 CFR 164.502\(a\)\(5\)\(iii\)\(B\)](#). The final rule text also adds the word “only” in [45 CFR 164.502\(a\)\(5\)\(iii\)\(B\)](#) to make clear that the prohibition's application is limited to the use or disclosure of PHI “only” where one or more of the conditions set forth in the Rule of Applicability exists.

To address concerns from commenters about how to determine whether reproductive health care is “lawful,” the Department finalizes a revised Rule of Applicability at [45 CFR 164.502\(a\)\(5\)\(iii\)\(B\)](#). Specifically, the Rule of Applicability, as finalized, requires that a regulated entity that receives a request for PHI make a reasonable determination about the lawfulness of the reproductive health care in the circumstances in which such health care was provided, where lawfulness is described by [45 CFR 164.502\(a\)\(5\)\(iii\)\(B\)\(1\)-\(3\)](#). Thus, a regulated entity that receives the request for PHI must decide whether it would be reasonable for a similarly situated regulated entity to determine, as provided in the Rule of Applicability, that the reproductive health care is lawful under the circumstances in which such health care is provided.

To make the reasonableness determination, that is, to determine whether it would be reasonable for a similarly situated regulated entity to determine that one or more of the conditions of the Rule of Applicability applies, a regulated entity receiving the request for PHI must evaluate the facts and circumstances under which the reproductive health care was provided. Such facts and circumstances include but are not limited to the individual's diagnosis and prognosis, the time such health care was provided, the location where such health care was provided, and the particular health care provider who provided the health care. This approach is consistent with the current and longstanding practice under the Privacy Rule, whereby a covered entity is responsible for determining whether a requested use or disclosure is permitted under one or more of the permissions set forth in the Privacy Rule. For example, a regulated entity is permitted to make a use or disclosure of PHI where “required by law” pursuant to [45 CFR 164.512\(a\)](#). To make a use or disclosure under that permission, the regulated entity cannot rely on assertions from the person making the request, but rather, must itself evaluate the relevant law to determine whether ***33014** the use or disclosure is “required by law” and thus permitted under that permission. As discussed above, the Department recognizes that this approach may prevent uses or disclosures in support of some law enforcement investigations (e.g., where a health care provider reasonably determines that its provision of reproductive health care was lawful, but where law enforcement reasonably disagrees or does not provide sufficient factual information for a regulated entity to determine that there is a substantial factual basis that the reproductive health care was not lawful under the circumstances in which such health care was provided). However, we believe that, in these narrow circumstances, the interests of law enforcement, and private parties afforded legal rights of action, are outweighed by privacy interests and that the current approach strikes the appropriate balance between these competing interests.

The Department is retaining the proposed framework for identifying the circumstances in which reproductive health care is lawful, and thus the prohibition applies. However, we are modifying the regulatory text of the Rule of Applicability to clarify its conditions. As revised, the regulatory text combines the first and third conditions of the Rule of Applicability into a revised [45 CFR 164.502\(a\)\(5\)\(iii\)\(B\)\(1\)](#) that focuses on whether the reproductive health care at issue is lawful under the circumstances in which such health care is provided. Under the revised condition, the circumstances in which the prohibition applies are determined by the law of the state in which the health care is provided.

As proposed in the 2023 Privacy Rule NPRM, the first and third conditions, when considered together, would have given the impression that the Department was drawing a distinction between reproductive health care provided in-state or out-of-state, although outcomes would have been the same. As the Department explained in the proposed rule, both the first and third conditions would have prohibited a regulated entity from using or disclosing PHI where the reproductive health care was permitted by the law of the state in which it was provided (e.g., for pregnancy termination that occurs before a state-specific gestational limit or under a relevant exception in a state law restricting pregnancy termination such as when the pregnancy is the result of rape or incest or because the life of the pregnant individual is endangered, for reproductive health care that is generally permitted but must be provided by a specific type of health care professional or in a certain place of service). The outcome of the analysis remains the same under this final rule, which combines the first and third conditions of the Rule of Applicability into one condition. Thus, the revision improves the clarity of the Rule of Applicability by focusing solely on whether the reproductive health care was lawful under the circumstances in which it was provided.

Additionally, the final rule modifies the regulatory text in [45 CFR 164.502\(a\)\(5\)\(iii\)\(B\)\(2\)](#) to include an express reference to the U.S. Constitution as a source of Federal law for determining whether reproductive health care is lawful under the circumstances in which such health care is provided. The Department has always intended to include the U.S. Constitution as a source of Federal law, and the final regulatory text now explicitly reflects this. The regulatory text also makes clear that the U.S. Constitution is not the sole source of Federal law and that Federal statutes, regulations, and policies may be the relevant legal authority for determining whether the reproductive health care is protected, required, or authorized under Federal law. This final rule in no way supersedes applicable state law pertaining to the lawfulness of reproductive health care.

To address commenters' concerns about obligating regulated entities to determine whether reproductive health care that occurred outside of the regulated entity is lawful, the Department is adding a new presumption provision at [45 CFR 164.502\(a\)\(5\)\(iii\)\(C\)](#). It presumes the reproductive health care at issue was lawful under the circumstances in which such health care was provided when it was provided by a person other than the regulated entity receiving the request. The presumption can be overcome

where the regulated entity has either actual knowledge, or factual information supplied by the person requesting the use or disclosure, that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided. The first ground to overcome the presumption—concerning “actual knowledge”—accounts for situations where the regulated entity has actual knowledge that the reproductive health care was not lawful. The second ground to overcome the presumption—concerning “factual information”—accounts for situations where the person making the request has demonstrated to the regulated entity that there is a substantial factual basis that the reproductive health care was unlawful under the circumstances in which such health care was provided. To satisfy the second ground, the regulated entity must obtain from the person making the request sufficient threshold factual evidence that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the circumstances in which such health care was provided.

For example, an investigator requests information from a health plan about claims for coverage of certain reproductive health care provided by a particular health care provider. The health plan must presume that the reproductive health care was lawful unless the health plan has actual knowledge that the reproductive health care was not lawful or the investigator supplied information that demonstrates a substantial factual basis to believe that the reproductive health care was not lawful under these circumstances. The latter condition could be met where the investigator provides the regulated entity with various types of documentation. For example, persons requesting PHI could provide the regulated entity with affidavits supplied by complainants that contain the circumstances under which the reproductive health care was provided. In this example, the presumption would be overcome, and the health plan would be permitted to use or disclose the PHI, assuming that all applicable conditions of the Privacy Rule were otherwise met. In contrast, if the investigator requests the same information but only provides an anonymous report of a particular health care provider providing reproductive health care that is not lawful under the circumstances in which it is provided, the health plan would not have a substantial factual basis to believe that the reproductive health care was not lawful. Accordingly, this final rule would prohibit the health plan from disclosing the requested PHI unless the investigator provides sufficient information to overcome the presumption and the use or disclosure is otherwise permitted by the Privacy Rule. The conditions of making the use or disclosure would include, as described elsewhere in this final rule, obtaining a valid attestation if the relevant permission requires one.

The Department emphasizes that, as demonstrated by the numerous comments on this issue, this regulatory presumption is necessary for workability by the regulated entities subject to this final rule. We recognize that when a regulated entity did not provide the reproductive health care at ***33015** issue, it may not have access to all of the relevant information, including medical records with the necessary information, to determine whether prior reproductive health care obtained by an individual was lawful. We clarify that regulated entities are not expected to conduct research or perform an analysis of an individual's PHI to determine whether prior reproductive health care was lawful under the circumstances in which it was provided when such health care was provided by someone other than the regulated entity that receives the request for the use or disclosure of PHI.

We also reiterate that this final rule is intended to support and clarify the privacy interests of individuals availing themselves of lawful reproductive health care, and not to thwart the interests of states in conducting lawful investigations or imposing liability on the provision of unlawful reproductive health care. While this new regulatory presumption may make it more difficult for a state to investigate whether reproductive health care was unlawful under the circumstances in which it was provided (e.g., when other sources of information that is not PHI are unavailable), as discussed above, the Department has considered those interests and determined that the effects are justified by countervailing privacy benefits. Moreover, as also explained above, society's interest in obtaining PHI in such circumstances is reduced, particularly in light of its continued ability to obtain information from other sources. The Department also emphasizes that it is not applying a blanket presumption that all reproductive health care reflected in a regulated entity's records was lawful under the circumstances in which it was provided. Instead, the presumption applies only where the reproductive health care at issue is provided by someone other than the regulated entity that received the request for the use or disclosure of PHI, and it may be overcome in the circumstances identified above.

In contrast, where a request for PHI is made to the regulated entity that provided the relevant reproductive health care, the regulated entity is responsible for determining whether it provided reproductive health care that was lawful under the

circumstances in which it was provided, including, as discussed above, a review of all available relevant evidence bearing on whether the reproductive health care was lawful under the circumstances in which it was provided. If the regulated entity reasonably determines that the health care was lawfully provided, the prohibition applies, and the regulated entity may not make the use or disclosure.

To illustrate how the presumption would apply, consider a hospital that has PHI about the provision of reproductive health care by a different facility. The hospital is not expected to conduct research or perform analysis into whether reproductive health care obtained at a different facility from another health care provider was lawful under the circumstances in which such health care was provided. Accordingly, the regulated entity, if they receive a request for PHI to which the prohibition at [45 CFR 164.502\(a\)\(5\)\(iii\)](#) may apply, is not expected to review the individual's PHI to determine the lawfulness of the prior reproductive health care. In such situations, the regulated entity is also not expected to research other states' laws to determine whether the reproductive health care was lawful under the circumstances in which it was provided, nor are they expected to consult with an attorney to do the same. Rather, the presumption standard allows the regulated entity to limit their review to information supplied by the person making the request for the use or disclosure of PHI where the request addresses reproductive health care provided by someone other than the regulated entity receiving the request. Thus, a regulated entity that did not provide the reproductive health care must presume that the reproductive health care was lawful under the circumstances in which it was provided unless the conditions of rebutting the presumption are met.

Consider a different example in which a law enforcement official from State A issues a subpoena to a hospital in State A to request the PHI of an individual from State A who is suspected of obtaining reproductive health care in State B that would have been unlawful under the law of State A if provided there. The hospital did not provide the reproductive health care in question, nor did the individual provide information to the hospital about who may have provided such health care. At the time the law enforcement official issues the subpoena, the individual is no longer in the hospital, nor is the individual receiving treatment at the hospital. Additionally, the law enforcement official provided no information in the subpoena that would make it reasonable for the hospital to determine that the reproductive health care at issue was not lawful in the circumstances in which it was provided, that is, to determine that the reproductive health care was not lawful under the law of State B or was not protected, required, or authorized by Federal law. In this case, the hospital did not have actual knowledge that, nor did the information supplied to it by the law enforcement official making the request demonstrate to the hospital a substantial factual basis that, the individual had previously received unlawful reproductive health care; therefore, the reproductive health care is presumed to have been provided under circumstances in which it was lawful to provide such health care. Accordingly, this final rule would prohibit the hospital from disclosing the requested PHI unless the law enforcement official provides sufficient information to overcome the presumption and the use or disclosure is otherwise permitted by the Privacy Rule. This includes, as described elsewhere in this final rule, receipt of a valid attestation if the relevant permission requires one.

Conversely, if the hospital is provided with factual information that demonstrates a substantial factual basis that the reproductive health care at issue was not lawful under the specific circumstances in which such health care was provided, the presumption would be overcome. When a presumption is overcome or rebutted, the Rule of Applicability at [45 CFR 164.502\(a\)\(5\)\(iii\)\(B\)](#) cannot be satisfied (i.e., the regulated entity has actual knowledge, or has received factual information from the person requesting the PHI to determine that there is substantial factual basis to believe, that the reproductive health care was not lawful under the circumstances in which it was provided), and thus, the use or disclosure would not be prohibited under the final rule. As such, the Privacy Rule would permit, but would not require, the hospital to disclose the PHI in response to the subpoena where the use or disclosure meets the requirements of an applicable permission, including the receipt of a valid attestation where required.

In another example, a law enforcement agency presents a covered entity's business associate, such as a cloud service provider, with a subpoena for the PHI of an individual who received reproductive health care as part of its investigation into the health care provider who provided such health care for the provision of that health care. The PHI is encrypted, and the business associate does not have the key to decrypt it or is not permitted under the terms of its business associate agreement with the covered entity to decrypt the PHI. Thus, the business associate lacks a complete view of the individual's PHI and did not provide ***33016** the underlying reproductive health care. Additionally, the business associate has no actual knowledge that the reproductive health

care was unlawful, nor did the person requesting the PHI supply it with information that demonstrates to the business associate a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided. In such a case, the presumption that the reproductive health care at issue was lawful applies. If the law enforcement agency does not present more information to overcome the presumption, the Privacy Rule prohibits the business associate from disclosing the requested PHI in response to the subpoena, even if the law enforcement agency has provided an attestation; in this circumstance, the attestation would not be valid because the disclosure is for a purpose that is prohibited by 45 CFR 164.502(a)(5)(iii).

The presumption serves a different purpose than the attestation, which is required when there is a request for PHI potentially related to reproductive health care for certain permitted purposes under the Privacy Rule, as discussed further below. In contrast with the attestation, the presumption applies only where a request for PHI involves a purpose prohibited under 45 CFR 164.502(a)(5)(iii) and the reproductive health care at issue was provided by someone other than the regulated entity that received the request for PHI, so the regulated entity does not have first-hand knowledge of the circumstances in which the reproductive health care was provided. Because the situations in which the presumption applies involve purposes prohibited under 45 CFR 164.502(a)(5)(iii), it is not reasonable for a regulated entity to rely, without additional information, on a statement from the person requesting the use or disclosure, including the statement required in the attestation by 45 CFR 164.509(b)(1)(ii), that the request is not made for a prohibited purpose or that the underlying reproductive health care was unlawful. Thus, such statement alone does not satisfy 45 CFR 164.502(a)(5)(iii)(C)(2). However, if a person requesting the use or disclosure of PHI provides the regulated entity with sufficient information, separate and distinct from the attestation itself, that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided, the presumption would be overcome; in this scenario, the Privacy Rule would permit, but would not require, the regulated entity to disclose the PHI in response to the subpoena. The presumption may also be overcome by, for example, a spontaneous statement from the individual about the circumstances under which they obtained reproductive health care.

As we explained above, this final rule, consistent with the Department's longstanding approach to the Privacy Rule, balances competing interests between the privacy expectations of individuals and society's interests in PHI for certain non-health care purposes. For example, since its inception, the Privacy Rule has permitted a covered entity to rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s).[FN297] Elsewhere in the Privacy Rule, covered entities are required to make a determination of whether it is "reasonable under the circumstances" to rely on documentation, statements, or representations from a person requesting PHI to verify the identity of the person requesting PHI and the authority of the person to access the PHI. [FN298] In the case of public officials, we have previously explained that covered entities must verify the identity of the request by examination of reasonable evidence, such as written statement of identity on agency letterhead, an identification badge, or similar proof of official status. In addition, where explicit written evidence of legal process or other authority is required before disclosure may be made, a public official's proof of identity and oral statement that the request is authorized by law are not sufficient to constitute the required reasonable evidence of the legal process or authority.[FN299] In both instances, the Privacy Rule permits regulated entities to rely on representations made by public officials where it is reasonable to do so but makes clear that in some instances, documentary or other evidentiary proof is needed.[FN300]

In this final rule, the Department has enshrined the requirement that a regulated entity make a reasonable determination of whether PHI should be disclosed in response to a request from law enforcement, or other official, in regulatory text and determined that is not reasonable to rely solely on representations of law enforcement or other officials without a written attestation. This approach is due to the high potential for harm to the individual who is the subject of the PHI or to persons who are subject to liability for the mere act of seeking, obtaining, providing or facilitating reproductive health care.

Further, as we discussed above, even in the scenario where a state official seeks PHI to investigate whether the underlying reproductive health care was unlawful, a regulated entity's reasonable determination that the conditions of the prohibition set

forth in the Rule of Applicability are met means that the prohibition applies and the regulated entity is prohibited from using or disclosing the PHI. This does not foreclose the ability of state officials to investigate the circumstances surrounding the provision of the reproductive health care, including through the collection of information from sources that are not regulated under HIPAA, to determine whether a health care provider or other person may have acted unlawfully. Rather, this final rule prohibits the use or disclosure of PHI when it is being used to investigate or impose liability on a person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care, or to identify any person to initiate such activities. Indeed, the individual's privacy interests are especially strong where individuals seek lawful reproductive health care and risk either avoiding such lawful health care or being less than truthful with their health care providers because they fear that their PHI will be disclosed.

The Department is re-designating proposed 45 CFR 164.502(a)(5)(iii)(B) as 45 CFR 164.502(a)(5)(iii)(D) and modifying it in response to the *33017 commenters who provided examples of situations where they could reasonably expect to receive a request for PHI that might relate to “seeking, obtaining, providing, or facilitating reproductive health care.” To address these concerns, the Department is revising the list of activities in 45 CFR 164.502(a)(5)(iii)(D) that explain the scope of actions taken by persons that the Department is protecting against impermissible requests for PHI. Specifically, the Department is adding the terms “administering,” “authorizing,” “providing coverage for,” “approving,” and “counseling about” to the current list of descriptive activities in the proposed rule and removing “inducing” from the list. We are removing “inducing” from the list in response to concerns from commenters that the prohibition might apply in circumstances where individuals are coerced to obtain reproductive health care. It was never the Department's intention for the prohibition on the use or disclosure of PHI to apply in such circumstances. Rather, we intended it to refer to situations in which a health care provider “induces” labor under circumstances in which such health care is lawful; however, we believe our intended meaning of “inducing” is encompassed in other terms in the list. The revised list better explains the type of activities in which a person may be engaged and about which the Department intends to prevent the use or disclosure of PHI.

The Department is not finalizing a separate Rule of Construction because the need is obviated by incorporating the key content into the prohibition itself at 45 CFR 164.502(a)(5)(iii). The Department proposed the Rule of Construction to clarify that 45 CFR 164.502(a)(5)(iii) should not be construed to prohibit a use or disclosure of PHI otherwise permitted by the Privacy Rule unless such use or disclosure is “primarily for the purpose of” investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care. By incorporating the Rule of Construction into the main standard and removing the proposed “primarily for the purpose of” language, the Department now more clearly conveys its intent to prohibit the use and disclosure of PHI for the specified purposes only when it relates to the “mere act of” seeking, obtaining, providing, or facilitating reproductive health care. As discussed in greater detail below in our responses to comments, this change is designed to reduce confusion for regulated entities about how to reconcile and apply the Rule of Construction with the main prohibition standard and does not change the scope of the prohibition as proposed. The revisions and restructuring of regulatory text formerly included in the Rule of Construction improve readability and reduce redundancy. Likewise, the final rule incorporates other minor wording changes to improve readability and updates regulatory text references to other paragraphs to accurately reflect the organization of this section.

Comment: Many commenters expressed support for the Department's proposal to create a new category of prohibited uses and disclosures about reproductive health care. A few of these commenters explained the rationale for their support as based on the proposed approach's balance of preventing harm to individuals from certain uses and disclosures and permitting beneficial uses and disclosures, while providing regulated entities with clarity with respect to when uses and disclosures of PHI would be permitted.

A few commenters agreed with the Department's view that a purpose-based prohibition is preferable to other approaches to protecting the privacy of individuals that would require labeling or segmenting of PHI. Other commenters focused on how the proposal would better facilitate HIPAA's goals of providing high-quality health care and encouraging the flow of information to covered entities.

Response: The approach we are taking in this final rule preserves the ability of regulated entities to use and disclose PHI for permitted purposes while also enhancing protections for PHI, to strike the appropriate balance between privacy interests and other societal interests, including law enforcement. As discussed above, the Department's approach will lead to numerous benefits associated with enhanced privacy protections.

Comment: A few commenters asserted that the Department's proposal would provide a consistent standard for all states to follow.

Response: The Department believes this final rule will provide clear standards for regulated entities, especially health care providers, by incorporating the prohibition into the Privacy Rule. However, we stress that the prohibition attaches to only requests for uses and disclosures that are for a prohibited purpose where the reproductive health care is lawful under the circumstances in which such health care is provided. Different states and localities have promulgated different standards for the lawfulness of reproductive health care.

Comment: A few commenters expressed their appreciation that the proposal encompassed a broad range of reproductive health care and explained the importance of ensuring that a final rule protects any health information about reproductive health care.

Response: As the Department acknowledged in the 2023 Privacy Rule NPRM, many routine medical examinations and treatments could involve PHI about an individual's reproductive health or reproductive organs and systems. This final rule is not limited to PHI about abortion. The Department recognized the impracticability of attempting to parse out the types of reproductive health care that should be subject to the prohibition and those that should not be. For this reason, and in keeping with the existing scheme of the Privacy Rule, the Department proposed and is finalizing a purpose-based approach to prohibiting the use and disclosure of any PHI for use against any person for seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided. A regulated entity that receives a request for PHI is charged with making a reasonable determination of whether the conditions of lawfulness set forth in the Rule of Applicability apply. To further assist regulated entities in understanding the broad scope of "reproductive health care," we provide in the preamble a non-exclusive list of examples that fit within the definition.

Comment: Some commenters expressed opposition to this proposal, asserting that the proposed new category would interfere with the enforcement of state laws that restrict or regulate abortion or that the proposal would make it more difficult for regulated entities to determine whether a requested use or disclosure of PHI is permitted under the Privacy Rule because it lacked sufficient specificity.

Response: The Department is finalizing a narrowly tailored prohibition that will only apply when an individual's privacy interest in lawfully obtained reproductive health care outweighs society's interest in obtaining PHI for non-health care purposes. As discussed above, the Department has adopted an approach that strikes the appropriate balance between privacy interests and other interests, including law enforcement interests in accessing PHI to investigate or impose liability on persons for seeking, obtaining, providing, or facilitating reproductive health care that ***33018** is unlawful under the circumstances in which such health care is provided. To help regulated entities operationalize the prohibition, the Department is finalizing an attestation requirement in [45 CFR 164.509](#) in which persons requesting PHI under a permission that is mostly likely to be used to request PHI for a purpose prohibited by [45 CFR 164.502\(a\)\(5\)\(iii\)](#) must attest that the request is not subject to the prohibition. The Department acknowledges that requests for a purpose prohibited by [45 CFR 164.502\(a\)\(5\)\(iii\)](#) may be made pursuant to another applicable permission and reminds regulated entities that they must evaluate all requests made by a third party for the use or disclosure of PHI to ensure that they are not for a prohibited purpose. Requests not subject to the prohibition would still be subject to the conditions of the relevant permissions in the Privacy Rule. When requests for PHI meet the conditions for permissions in the Privacy Rule, including conditions specified in [45 CFR 164.512](#), regulated entities are permitted to use and disclose PHI in accordance with such permissions.

Moreover, as we describe above, the Department is modifying the final rule to clarify that the prohibition restricts the use and disclosure of PHI for the enumerated purposes when connected to the "mere act of" seeking, obtaining, providing, or facilitating

reproductive health care. Thus, the prohibition does not prevent the use or disclosure of the PHI about reproductive health care obtained by an individual in all circumstances. Rather, it prevents the use or disclosure of PHI when the purpose of the disclosure is to investigate or impose liability on a person because they sought, obtained, provided, or facilitated reproductive health care that was lawful under the circumstances in which such health care was provided, as determined by the regulated entity that received the request for PHI. For example, a regulated entity would not be prohibited from disclosing an individual's PHI when subpoenaed by law enforcement for the purpose of investigating allegations of sexual assault by or of the individual, assuming that law enforcement provided a valid attestation and met the other conditions of the permission under which the request was made.

Comment: A commenter expressed opposition to the proposal and asserted that it relied on the assumption that it would be readily apparent or ascertainable whether particular reproductive health care was lawfully provided. According to this commenter, persons who violate the law have an interest in concealing their activity, and the proposal would impede law enforcement investigations to determine whether lawbreaking has occurred. Additionally, the commenter expressed their concern that the proposal would represent a departure from the Privacy Rule's existing approach to law enforcement investigations and proceedings.

Response: The Department is finalizing a regulatory presumption to address the narrow circumstance of when lawfulness is not readily apparent to a regulated entity who is the recipient of a request for the use or disclosure PHI when the regulated entity did not provide the underlying reproductive health care. As we explained above, this final rule is intended to support and clarify the privacy interests of individuals availing themselves of lawful reproductive health care, and not to thwart the interests of states and the Federal government in conducting lawful investigations or imposing liability on the provision of unlawful reproductive health care. While this new regulatory presumption may make it more difficult for law enforcement officials to investigate whether reproductive health care was unlawful under the circumstances in which it was provided (e.g., when other sources of information that is not PHI are unavailable), the Department has considered those interests and determined that the effects are justified by countervailing privacy benefits. We also reiterate here that the presumption is not a blanket presumption. It only applies where the reproductive health care at issue is provided by someone other than the regulated entity that received the request for the use or disclosure of PHI, and it may be overcome in the circumstances identified above.

We note that the Privacy Rule has always and continues to permit regulated entities to disclose PHI for law enforcement purposes, subject to certain conditions or limitations. In this final rule, the Department has found that changes in the legal landscape now necessitate codifying a prohibition against uses and disclosures for the purposes specified in [45 CFR 164.502\(a\)\(5\)\(iii\)\(A\)](#), subject to the Rule of Applicability in [45 CFR 164.502\(a\)\(5\)\(iii\)\(B\)](#). The Department is not otherwise changing the existing permissions in the Privacy Rule that permit regulated entities to use or disclose PHI for law enforcement purposes and other important non-health care purposes, except as discussed elsewhere in this rule. These purposes include when PHI is required by law to be disclosed for purposes other than those prohibited by this final rule, for public health and health oversight activities, for other law enforcement purposes not in conflict with this rulemaking, for reports of child abuse, about decedents when not prohibited by this final rule, and other purposes specified in the Privacy Rule.

In particular, in the 2023 Privacy Rule NPRM, the Department discussed the interaction of this rule with HIPAA's statutory preemption provisions [FN301] and explained that it was necessary to preempt state laws that require the use and disclosure of PHI for the purposes prohibited by this rule to give effect to the prohibition consistent with HIPAA. As discussed above, to achieve the purpose for which HIPAA was enacted, to enable the electronic exchange of identifiable health information, we must protect the privacy of that information to further individuals' trust in the health care system. As finalized, the prohibition is limited only to circumstances in which the privacy interests of an individual and the interests of society in an effective health care system outweigh society's interest in obtaining PHI for non-health care purposes.

Comment: A commenter stated that, to the extent the ability of a state to determine whether to investigate or bring a proceeding is based on information in the possession of a regulated entity, the proposed rule did not adequately address a state's need to regulate the medical profession and health care facilities.

Response: As finalized, the prohibition prevents the use and disclosure of PHI for certain purposes where a person sought, obtained, provided, or facilitated reproductive health care that is lawful under the circumstances in which such health care is provided. As discussed above, the final rule strikes the appropriate balance between privacy interests and other interests. Public officials remain free to investigate the provision of health care by seeking information from non-covered entities. Moreover, the prohibition does not prevent a state from enforcing its laws. Instead, it protects the privacy of individuals' PHI in certain circumstances.

Comment: A few commenters expressed concern that the proposed prohibition may also affect the enforcement of Federal laws.

Response: The Department has consulted extensively with other Federal agencies and officials in the ***33019** development of this rule, including the Attorney General, and does not believe that this rule will impede the enforcement of Federal laws. As discussed above, this rule carefully balances privacy and other interests, applying only in certain narrowly tailored situations.

Comment: Numerous commenters recommended that the Department expand the scope of the proposed prohibition to include other or all types of stigmatized health care. A few commenters recommended expanding the proposed prohibition to all health care or to provide individuals the ability to prevent the disclosure of their PHI through HIEs.

Generally, commenters supporting expansion of the proposal's scope expressed the belief that it was necessary for HIPAA to promote trust between individuals and health care providers and to improve health care quality and outcomes.

Several commenters explained that persons seeking, obtaining, providing, or facilitating other types of health care are facing the same challenges as described in the proposal with respect to reproductive health care, including health care obtained outside of the health care system, and provided examples of such challenges. Many commenters also made recommendations for how the Department should address those challenges.

Response: The Department is issuing this final rule to protect the privacy of PHI when it is sought for activities to investigate or impose liability on persons for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care. Lawfulness is based on a reasonable determination made by a regulated entity that has received a request for PHI for one of the purposes specified at [45 CFR 164.502\(a\)\(5\)\(iii\)\(A\)](#) that at least one of the conditions in the Rule of Applicability applies. We are finalizing a prohibition that is not specific to certain procedures, laws, or types of providers. Rather, the prohibition we finalize here requires regulated entities to consider the purpose of the requested use or disclosure. To the extent that the specific types of health care referenced by commenters above meet the definition of reproductive health care, this final rule will prevent the disclosure of PHI where it is sought for activities with the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided. In adopting a purpose-based prohibition, the Department has chosen an administrable standard that reflects the appropriate balance between protecting individuals' privacy interests and allowing the use or disclosure of PHI in support of other important societal interests. Additional privacy protections for information about SUD treatment may be afforded to PHI in Part 2 records under Part 2.[FN302]

Comment: In response to the Department's specific request about whether it should require a regulated entity to obtain an individual's authorization for any uses and disclosures of "highly sensitive PHI" or otherwise address such a defined category of PHI in the Privacy Rule, a few commenters urged the Department to expand the proposed prohibition to protect all people at risk of criminal or other investigation for use of essential health care or care, services, or supplies related to the health of the individual that could expose any person to civil or criminal liability. Several commenters recommended that the Department expand the scope of the proposed prohibition to, variously, all "highly sensitive health information," "sensitive personal health care," "highly sensitive PHI," or "highly sensitive PHI and restricted health care service" because of the potential harms that could result if such health information were to be disclosed without stringent privacy safeguards.

Several commenters asserted that creating a category of or separate standard for “highly sensitive PHI” would cause significant confusion because it would be difficult to define in a commonly understood manner. According to these commenters, this would make compliance more challenging and costly and further decrease the individual's privacy. A few commenters expressed concern that creating a special category of highly sensitive PHI would further stigmatize certain types of health care.

Several commenters expressed concern that prohibiting or limiting uses or disclosures of highly sensitive PHI for certain purposes may negatively affect efforts to eliminate the need for data segmentation, such as efforts to align the Privacy Rule and Part 2; reduce or eliminate stigmatization of certain health conditions and diagnoses; and improve health care management and health care coordination.

Response: We appreciate these comments and generally agree with commenters who expressed concern that the Privacy Rule should address the shifting legal landscape to ensure that it continues to protect PHI, regardless of how the PHI is transmitted or maintained. We also agree that to the extent possible, the Privacy Rule should promote administrative efficiency and disincentivize adverse actions by health care providers grounded in fear of prosecution or legal risks borne from providing lawful health care to individuals, which may erode patients' trust and confidence in the health care system and deter them from seeking lawful health care. The Department's approach to promulgating a narrowly tailored prohibition focused on clarifying the use and disclosure of PHI for the purposes prohibited by this final rule accomplishes these goals. As we explained in the 2023 Privacy Rule NPRM and re-affirm in this final rule, recent developments in the legal environment have made information about lawful reproductive health care sought by or provided to an individual more likely to be of interest for punitive non-health care purposes, and thus more likely to be used or disclosed if sought for a purpose permitted under the Privacy Rule today. As explained, the Department has identified concerns that the use or disclosure of PHI for the prohibited purposes in this rule would erode individuals' trust in the privacy of legal reproductive health care. Such erosion would negatively affect relationships between individuals and their health care providers, result in individuals forgoing needed treatment, and make individuals less likely to share pertinent health concerns with their health care providers. Modifying the Privacy Rule to focus on and address this shifting landscape is the most efficient way to return to a regulatory landscape that is balanced and consistent with the goals of HIPAA.

We do not believe that it is necessary to modify the Privacy Rule to prohibit the use and disclosure of PHI for any criminal, civil, or administrative investigation or effort to impose criminal, civil, or administrative liability related to all health care, services, or supplies. Sections 164.512(e) and (f) already set forth the specified conditions under which regulated entities may disclose PHI for judicial and administrative proceedings and law enforcement purposes.

We decline to modify the prohibition to apply it to the use and disclosure of “highly sensitive PHI.” We are persuaded by commenters who voiced concern about the feasibility of defining the phrase such that regulated entities would be able to understand and ***33020** operationalize it. We also find persuasive comments about the compliance burden that would result from implementing such a prohibition. While PHI about reproductive health care may be found throughout an individual's record and may be collected or maintained by multiple types of providers, the term “reproductive health care” is defined in a manner that is clearly connected to the reproductive system, its functions, and processes.[FN303]

In contrast, applying the prohibition to all “highly sensitive PHI” or any use or disclosure of PHI that results in harm, stigma, or adverse result for an individual would be unworkable because of lack of consensus about how to define such categories and would likely create the issues with segmentation and care coordination discussed above. As discussed above, the purpose of this final rule and narrowly crafted prohibition is to adopt the appropriate balance in the Privacy Rule between protecting individuals' privacy and permitting PHI to be used and disclosed for other societal benefits. The commenters' objectives reflect a desire to protect individuals, but their discussion does not properly account for other societal interests that are supported by certain disclosures of PHI, interests that the Privacy Rule has balanced since its inception.

Comment: A commenter requested that the Department clarify that state laws may protect the privacy of health information when the Privacy Rule does not apply, such as when individuals' health information is in the possession of a person that is not a regulated entity, such as a friend or family member, or is stored on a personal cellular phone or tablet.

Response: HIPAA provides the Department with the authority to protect the privacy and security of IIHI that is maintained or transmitted by covered entities, and in some cases, their business associates. Other laws may apply where the HIPAA Rules do not. Guidance on protecting the privacy and security of health information when using a personal cell phone or tablet is available on OCR's website.[FN304]

Comment: Many commenters cited potential operational challenges with the proposed prohibition and confirmed that current health IT generally does not provide regulated entities with the ability to segment PHI into specific categories afforded special protections. A few commenters recommended that the Department work with EHR vendors to modernize health care data management platforms to better address data segmentation, while others recommended that the Department ensure interagency coordination of data segmentation policies and provide individuals with granular level of control over their PHI.

A few commenters requested that the Department address concerns about the interaction between the minimum necessary standard and this final rule.

A commenter asserted that privacy protections that do not account for individual privacy preferences would result in individuals withholding information from their health care providers, and some health care providers electing not to generate or document certain information from or about individuals.

Response: The prohibition, as finalized, should not implicate additional data segmentation concerns beyond those that already exist. We acknowledge the low adoption rate of data segmentation standards and challenges related to the technical and administrative feasibility of data segmentation (e.g., costs), and as discussed above, are finalizing a purpose-based approach to address such concerns. The Department continues its active engagement, particularly through ONC, to identify robust data sharing standards that facilitate appropriate privacy controls.

With respect to concerns about the Privacy Rule minimum necessary standard, we do not anticipate that this final rule will affect the ability of regulated entities subject to the standard to comply. First, the prohibition is applicable only for the purposed uses and disclosures specified in [45 CFR 164.502\(a\)\(5\)\(iii\)](#). Regulated entities must make reasonable efforts to limit the use or disclosure of PHI pursuant to [45 CFR 164.512](#), other than [45 CFR 164.512\(a\)](#), to the minimum amount of PHI necessary to accomplish the intended purpose of the use, disclosure, or request.[FN305] Regulated entities are required to have in place policies and procedures that outline how the entity complies with the standard.[FN306]

Comment: A few commenters requested that the Department clarify the roles and responsibilities of covered entities and business associates with respect to compliance with the proposed prohibition and attestation requirements and whether business associate agreements would need to be amended to reflect the requirements of the final rule.

Response: The prohibition standard finalized in [45 CFR 164.502\(a\)\(5\)\(iii\)\(A\)](#) applies directly to all regulated entities; meaning, all HIPAA covered entities and business associates. We also note that the finalized presumption of lawfulness for the underlying health care, when applicable, directly applies to business associates, as does the attestation requirement in [45 CFR 164.509](#). As such, business associates of covered entities that hold PHI by virtue of their business associate relationship with the covered entity are subject to the express prohibition on using or disclosing PHI for the specified purposes, regardless of whether the prohibition is specified in the business associate agreement. The attestation requirement and its application to business associates are discussed in greater detail below.

Comment: A commenter expressed support for the application of the proposal to health care providers, but also recognized states' interest in ensuring that health care providers render health care in accordance with the standard of care in that state. Another commenter questioned the Department's authority under HIPAA to implement this provision.

Response: The Department is modifying the proposed definition of "Reproductive health care" to explicitly clarify that the definition does not set a standard of care for or determine what constitutes clinically appropriate reproductive health care. Additionally, as discussed above, the application of this rule is limited to reproductive health care that is lawful under the circumstances in which such health care is provided as described at [45 CFR 164.502\(a\)\(5\)\(iii\)\(B\)](#). Lawfulness is determined by the regulated entity that receives the request for PHI, after a reasonable determination that at least one of the conditions in the Rule of Applicability apply. As explained above, the prohibition is carefully tailored to protect the privacy of individuals' health information in circumstances where the reproductive health care at issue was lawful under the circumstances such care was provided, reflecting the appropriate balance between privacy interests and other societal interests.

Comment: Many commenters recommended alternative or additional ***33021** approaches to the purpose-based prohibition, such as eliminating or narrowing the permissions for use or disclosure of PHI without an individual's authorization or limiting disclosures to third parties subject to an individual's authorization.

A few commenters recommended that the Department revise specific Privacy Rule permissions to clarify the use and disclosure of PHI for certain administrative or law enforcement requests, instead of promulgating a new prohibition.

Response: The Department's approach to prohibit the uses and disclosures of PHI for the purposes described in this final rule is consistent with the Privacy Rule's longstanding balancing of individual privacy interests with society's interests in PHI for non-health care purposes. Adopting the correct balance is necessary to preserve and promote trust between individuals and health care providers. Instead of modifying specific permissions at [45 CFR 164.512](#), we are finalizing modifications that prohibit the use or disclosure of PHI to ensure the correct balance, instead of modifying specific permissions at [45 CFR 164.512](#). Recognizing that requests that fall under these permissions represent important public policy objectives (e.g., health oversight, law enforcement, protection of individuals subject to abuse), the Department is imposing a new attestation requirement, as described in greater detail below, to protect against harm that may arise from the use or disclosure of PHI for a purpose prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#), which is more likely to occur when a person requesting the use or disclosure of PHI relies on certain permissions. The new attestation condition will also provide a mechanism that will enable a regulated entity to better evaluate the request. The Department declines to make additional changes at this time and will consider these topics for future guidance. The Department also declines to finalize its proposal to prevent an individual from requesting that a regulated entity use or disclose PHI pursuant to a valid authorization.

Comment: A few commenters questioned the ability of regulated entities to use or disclose PHI in compliance with mandatory reporting laws, such as laws requiring the reporting of suspected child abuse or domestic violence.

A few of these commenters questioned whether mandatory reporting requirements would change a regulated entity's duty to apply the minimum necessary standard.

A few commenters asserted that mandatory reporting laws dissuade individuals from seeking health care, prevent the development of trust between individuals and health care providers, and generally are implemented in an inequitable fashion that disproportionately apply to individuals from marginalized or historically underserved communities or communities of color.

Response: The Department acknowledges that there may be some mandatory reporting laws that require a regulated entity to determine whether a request for PHI is for a purpose prohibited by this rule. However, whether in response to a mandatory reporting law or routine request, the final rule's operation remains the same, that is, it prohibits a regulated entity from using or disclosing PHI for a prohibited purpose when the reproductive health care under investigation or at the center of the activity to impose liability is lawful under the circumstances that it was provided.

To the extent mandatory reporting requirements apply to the reporting of PHI to public health authorities for public health purposes, including PHI about reproductive health care, this final rule does not prevent a regulated entity from complying with such mandate.

To aid stakeholders in understanding how the prohibition operates with respect to public health reporting, the Department is clarifying that the term “Public health,” as used in public health surveillance, investigation, and intervention, includes identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of PHI. In so doing, we are clarifying that public health surveillance, investigation, and intervention are outside of the scope of activities prohibited by 45 CFR 164.502(a)(5)(iii). These changes will offer additional protection to individuals who would otherwise be subject to having their PHI disclosed for a prohibited purpose because the underlying mandatory reporting requirement did not clearly specify its relationship to public health. This final rule does not change the minimum necessary standard or the circumstances in which the Privacy Rule requires a regulated entity to apply the minimum necessary standard.

Comment: Many commenters expressed concern that the purposes for which the Department proposed to prohibit uses or disclosures would interfere with the ability of law enforcement to conduct investigations, including into coercion, child abuse, and sex trafficking and assault, would prevent states from verifying state licensure requirements, and would hamper the ability of health care professionals to report illegal behavior by other health care professionals.

Response: As discussed above, the prohibition applies only to activities conducted for the purpose of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is provided under circumstances in which such health care is lawful. A regulated entity is permitted to disclose PHI to a person who requests PHI for other purposes if a permission applies and the underlying conditions of the relevant permission are met, including the attestation condition, if applicable.

Comment: A few commenters recommended that the Department establish a safe harbor for the use or disclosure of PHI by regulated entities for TPO.

Response: We appreciate the comment but do not believe such a safe harbor is necessary. The Privacy Rule permits the disclosure of an individual's PHI for TPO when the conditions set forth in the TPO provisions of the rule are met.[FN307] The prohibited uses and disclosures codified in this rulemaking would rarely intersect with uses and disclosures that qualify as TPO activities. As explained above, to the extent a person requesting the use or disclosure of PHI reasonably articulates a basis for a request that is not related to the mere act of seeking, obtaining, providing, or facilitating reproductive health care, a regulated entity may use or disclose the PHI where otherwise permitted by the Privacy Rule.

Comment: A commenter recommended that the Department clarify that the prohibition applies to the activities of insurers and third-party administrators of self-funded plans by adding “administering, authorizing, covering, approving, or gathering or providing information about” to the explanation of “seeking, obtaining, providing, or facilitating.”

Response: The prohibition applies to all activities that a person could reasonably be expected to engage in with a regulated entity that could result in a use or disclosure of PHI that might be sought for prohibited purposes, including activities conducted or performed by or on behalf of a health *33022 plan, including a group health plan.[FN308] Accordingly, the Department has modified the scope of activities initially proposed in the 2023 Privacy Rule NPRM to better explain what it meant by seeking, obtaining, providing, or facilitating reproductive health care. The modified text is finalized at 45 CFR 164.502(a)(5)(iii)(D), [FN309] and adds administering, authorizing, providing coverage for, approving, counseling about to the non-exhaustive list of example activities.

Comment: Several commenters expressed support for the proposed Rule of Applicability. A few commenters expressed support for the proposed Rule of Applicability because it would reassure residents of the state in which the lawful health care is provided and individuals who travel to such states for lawful health care that their medical records will not be disclosed for prohibited purposes.

Response: We are finalizing a modified Rule of Applicability as described above.

Comment: Some comments expressed varying levels of support for the Department's references to "substantial interests" by states or superseding state laws. A few commenters disagreed with the Department's assertion that states lack a legitimate interest in conducting a criminal, civil, or administrative investigation or proceeding into lawful reproductive health care where the investigation is based on the mere fact that reproductive health care was or is being provided. Others asserted that the proposed rule would be unworkable and would assign health care providers and the Department the power to determine whether reproductive health care was provided lawfully, thereby affording them the authority to enforce certain state laws.

Response: As explained above, the Rule of Applicability reflects the Department's careful balancing of privacy interests and other societal interests. For the reasons explained above, the Department has determined that the privacy interest of an individual and the interest of society in an effective health care system outweigh the interests of society in seeking the use of PHI for non-health care purposes that could result in harm to the individual where a regulated entity that receives a request for PHI reasonably determines that at least one of the conditions in the Rule of Applicability applies. To help clarify this discussion further, the Department provides examples where the Rule of Applicability applies in this section of this final rule.

Comment: Several commenters recommended that the Department eliminate the distinction between health care that is lawful and health care that is not and that all forms of reproductive health care should be protected from criminalization and government investigation.

Several commenters stated that the term "lawful" would incorrectly suggest that receiving certain types of reproductive health care could be unlawful, even though most prohibitions on reproductive health care apply to providing or performing the health care, rather than receiving it. They also questioned whether the proposed Rule of Applicability would protect individuals who obtained reproductive health care in another state.

Response: We are finalizing a Rule of Applicability at [45 CFR 164.502\(a\)\(5\)\(iii\)\(B\)](#) that ensures the privacy of PHI when it is sought to conduct an investigation into or impose liability on any person for the mere act of seeking, obtaining, providing or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided, consistent with applicable Federal or state law. A regulated entity that receives a request for PHI must make a reasonable determination that at least one of the conditions in the Rule of Applicability applies. As discussed above, this approach reflects a careful balance between privacy interests and other societal interests.

Comment: Some commenters asserted that medical records should not be used for purposes outside of the health care setting in ways that could harm the subject of the records, particularly for law enforcement or other governmental purposes. One commenter expressed concern that disclosures of PHI would not be limited for all purposes, and that the proposal would not prevent a state from pursuing actions where the health care is later found to be unlawful. Another commenter asserted that disclosing PHI to law enforcement in connection with an investigation into reproductive health care is a secondary use of PHI that would be directly at odds with the purpose for which the PHI was collected, while others stated that the proposal risks deterring individuals from seeking or obtaining necessary health care.

A few commenters expressed concerns that health care providers could be inhibited from providing necessary health care, fully educating individuals about their options, or documenting the health care provided.

Response: When the Department promulgated the 2000 Privacy Rule, we acknowledged that the rule balanced the privacy interests of individuals with the interests of the public in ensuring PHI was available for non-health purposes. As we explained in the 2023 Privacy Rule NPRM, “individuals’ right to privacy in information about themselves is not absolute. It does not, for instance, prevent reporting of public health information on communicable diseases or stop law enforcement from getting information when due process has been observed.” [FN310] At the same time, in the 2023 Privacy Rule NPRM, the Department acknowledged that adverse consequences do result when individuals question the privacy of their health information and explained that the purpose of HIPAA is to protect the privacy of information and promote trust in the health care system to ensure that individuals do not forgo lawful health care when needed or withhold important information that may affect the quality of their health care.[FN311]

Accordingly, the Privacy Rule provides a clear framework to operationalize these principles, and this final rule is intended to balance these interests. The Privacy Rule does not protect information received or maintained by entities other than those that are regulated under HIPAA, including information that is used for a purpose other than the purpose for which it was initially requested. This final rule provides heightened protection, as necessary, to the privacy of PHI where its use or disclosure may result in harm to a person in connection with seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided. With respect to other disclosures to law enforcement or to other governmental interests, the Privacy Rule includes other carefully crafted permissions that specify the conditions under which such disclosures must be made to ensure a reasonable balance between privacy and the public policies that disclosure would serve.

Comment: Several commenters asserted that the proposed Rule of Applicability would not protect all PHI pertaining to lawful health care. For example, commenters suggested that the proposed Rule of Applicability would be unlikely to protect individuals who *33023 obtain care outside of the health care system and urged the Department to clarify the final rule to strengthen protections for individuals who receive care in this manner. As another example, a commenter expressed concern that the proposal would not protect PHI for individuals who obtain legal reproductive health care, but as a result of complications, subsequently access health care in a state where the same reproductive health care is illegal.

Response: The definition of “reproductive health care” is discussed in greater detail above. As noted above, this final rule does not establish a standard of care, nor does it regulate what constitutes clinically appropriate health care.

Commenters who point out that different results may arise in different states are correct, but this has been true since the inception of the Privacy Rule because it sets a national floor for privacy standards, rather than a universal rule. The prohibition applies, and therefore liability attaches, when the prohibition is violated, based on the “circumstances in which such health care is provided.” Thus, a regulated entity is not permitted to disclose PHI about reproductive health care that was provided in another state where such health care was provided under circumstances in which it was lawful to provide such health care, even where the individual subsequently accesses related health care in a state where it would have been unlawful to provide the underlying health care under the circumstances in which such health care was provided. HIPAA liability attaches in cases where attempts to circumvent the Privacy Rule result in impermissible or wrongful uses or disclosures.[FN312]

We remind regulated entities that the Privacy Rule permits the use or disclosure of PHI, without an individual’s signed authorization, only as expressly permitted or required by the Privacy Rule. For example, where state or other applicable law prohibits certain reproductive health care but does not expressly require a regulated entity to report that an individual obtained the prohibited health care, the Privacy Rule would not permit a disclosure to law enforcement or other investigative body pursuant to the “required by law” permission (but could potentially allow it pursuant to other provisions).[FN313]

Comment: One commenter recommended the Department add language to the proposed Rule of Applicability or elsewhere to ensure that there would be protections for PHI where a health care provider believes the health care is legal, even when the person requesting the use or disclosure of PHI disputes the legality. A few commenters asserted that the health care provider

making the decision could be a party to the reproductive health care at issue, making it a conflict of interest for the health care provider to make the determination regarding the lawfulness of the reproductive health care.

Response: We do not believe additional language is necessary because, under the prohibition, the regulated entity—and not the person making the request—is responsible for reasonably determining whether health care was lawful before making a disclosure. As explained above, this framework is consistent with how the Privacy Rule's permissions are administered, whereby regulated entities must determine whether a use or disclosure is permitted under the relevant permission. For example, when evaluating whether a use or disclosure of PHI is permitted because the use or disclosure is required by law, the regulated entity must look to the relevant law to determine whether the use or disclosure falls within that permission.[FN314] Furthermore, as with other use and disclosure provisions in the Privacy Rule, regulated entities remain subject to HIPAA liability for impermissible or wrongful disclosures. Neither the statute nor the Privacy Rule provides an exception to such liability for circumstances involving conflicts of interest.

Comment: Many commenters expressed concern regarding the burden imposed upon and resources that would be required for regulated entities to determine whether the reproductive health care at issue was lawful if they did not provide the health care at issue, particularly considering the evolving nature of state law in this area. Several commenters expressed concern that the proposal incorrectly assumes that regulated entities would know where the reproductive health care at issue occurred and inquired about specific scenarios, such as where requests for PHI are received by clinical laboratories that have no face-to-face interaction with individuals and that rely on information provided by other covered entities. A few commenters asserted that requiring regulated entities to make the required legal determinations would not be conducive to building a trusting relationship between individuals and health care providers.

Some commenters offered recommendations to the Department, such as providing guidance for health care providers regarding their rights and responsibilities under a final rule, revising the proposal to clarify that there would be a presumption that reproductive health care occurred under lawful circumstances, absent compelling evidence to the contrary, particularly when an individual travels for health care, and clarifying the Rule of Applicability by including examples in the regulatory text.

Some commenters asserted that regulated entities in different states or with different interpretations of certain state requirements could reach different determinations about whether the reproductive health care was provided lawfully, in part because of the lack of clarity or consistency in the interpretation in these laws. Yet another commenter recommended that the Department add an express directive that, in the event of any ambiguity or unsettled law, the scope of what is considered lawful should be interpreted consistently with the intent of the rule to protect the privacy of PHI to the maximum extent possible. A commenter recommended that where the regulated entity decides in good faith, it should not be subject to penalties or enforcement action if their determination is incorrect or if the Department disagrees with the determination. Another commenter recommended that the Department clarify that regulated entities may use a reasonableness standard when making the determination about whether state laws conflict with the Privacy Rule and are therefore preempted by HIPAA.

A few commenters expressed concern about the potential interpretation or application of the proposed Rule of Applicability, particularly when the laws at issue are ambiguous. Commenters recommended inclusion of language that PHI need not be disclosed to a government agency or law enforcement if the health care provider deems, in good faith, that the reproductive health care is lawful under the circumstances in which it is provided, and that the Department clarify the application of preemption or provide in preamble examples of each condition of the proposed Rule of Applicability.

Response: We appreciate the many comments the Department received in response to its inquiry asking whether the proposed Rule of Applicability would be sufficiently clear to individuals and covered entities, and ***33024** whether the provision should be made more specific or otherwise modified. Considering the many comments expressing concern about the burden associated with, the difficulty of, or the liability that could attach when someone other than the person who provided the health care must determine whether the underlying reproductive health care is lawful, the Department is adding a regulatory presumption in the final rule.

As discussed above, the regulatory presumption in 45 CFR 164.502(a)(5)(iii)(C) will permit a regulated entity receiving a PHI request that may be subject to the prohibition to presume the reproductive health care at issue was lawful under the circumstances in which such health care was provided when provided by a person other than the regulated entity receiving the request. The presumption includes a knowledge requirement such that the regulated entity must not have actual knowledge that the reproductive health care was unlawful under the circumstances in which such health care was provided or factual information supplied by the person requesting the use or disclosure of PHI that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided.

Comment: A commenter asserted that the proposed rule would unlawfully thwart enforcement of Federal criminal laws on reproductive health care because the proposed rule would be limited to circumstances where reproductive health care is permitted by state law, thereby prohibiting disclosures for the purpose of enforcing Federal laws pertaining to reproductive health care when they conflict with state law. A few commenters expressed their support for the Department's proposal that the prohibition against the use or disclosure of PHI apply where certain Federal laws apply. A few commenters requested greater specificity with respect to the application of Federal and state laws on abortion.

Response: Federal laws that involve reproductive health care form the underlying basis for examining whether reproductive health care was protected, required, or authorized by Federal law under the circumstances in which it was provided, pursuant to the 45 CFR 164.502(a)(5)(iii)(B)(2). Under this final rule, Federal and state authorities retain the ability to investigate or impose liability on persons where the investigation or imposition of liability is centered upon the provision of reproductive health care that is unlawful under the circumstances in which it is provided. As discussed above, this rule reflects a careful balance between privacy interests and other societal interests, and the prohibition is tailored to cover situations where the reproductive health care was lawfully provided, whether state or Federal law is at issue.

Comment: A few commenters provided examples of and expressed concerns about the electronic availability of PHI about health care lawfully provided in one state to health care providers in another state where such health care would not have been lawful.

A few commenters requested that the Department clarify that clinical laboratory testing involving a validated laboratory-developed test used within a single laboratory certified pursuant to the Clinical Laboratory Improvement Amendments of 1988 [FN315] (CLIA) and the implementing regulations, an in vitro diagnostic test cleared or approved by the Food and Drug Administration (FDA), or a validated laboratory-developed test that is an in vitro diagnostic test cleared or approved by the FDA and used within a single CLIA-certified laboratory would fall within the scope of reproductive health care that would be “authorized by Federal law” for the purposes of the Rule of Applicability. The commenters also recommended that a clinical laboratory test furnished under the authority of a state with legal requirements that are equal to or more stringent than CLIA's statutory and regulatory requirements, and is therefore exempt from CLIA requirements, also be considered “authorized by Federal law” for the purposes of the Rule of Applicability.

Response: We interpret the language “authorized by Federal law” in the Rule of Applicability to include activities, including clinical laboratory activities, that are conducted as allowed under applicable Federal law, in circumstances where there is no conflicting state restriction on the Federally authorized activity or where applicable Federal law preempts a contrary state restriction. In such circumstances, these activities are lawfully conducted because there either is no relevant state restriction or Federal law preempts a contrary state restriction. This provision thus reflects the Department's careful balancing of privacy interests and other societal interests in disclosure. As explained above, in circumstances where reproductive health care is lawfully provided, privacy interests are heightened while other societal interests in disclosure are reduced. This final rule and the operation of HIPAA's general preemption authority do not supersede applicable state law pertaining to the lawfulness of reproductive health care.

Comment: One commenter expressed support for including the phrase “based primarily” to clarify that the proposed Rule of Construction would only address situations where the purpose of the disclosure is to investigate or impose liability because

reproductive health care was provided, rather than for an issue related to, but not focused on the provision of such health care, such as the quality of the health care provided or whether claims for certain health care were submitted appropriately.

All other commenters recommended removing “primarily” to ensure that there is consistent implementation. In the alternative, the commenters recommended that the Department provide additional examples of scenarios in which a situation would and would not be considered “primarily for the purposes of” or “primarily based on” the provision of reproductive health care. One commenter asserted that the definition is uncertain and could be interpreted as permitting secondary or additional uses or disclosures. Another commenter explained that permitting a use or disclosure where conducting the investigation or imposing liability is only for a secondary or incidental purpose would create too much risk for individuals and health care providers and would undermine the intent of the proposed prohibition. And another stated it is foreseeable that a requesting entity could still use the PHI for one of the purposes for which the Department proposed to prohibit uses or disclosures of PHI once they have it if it was not the primary purpose of their request. A commenter expressed concern that the language could be exploited to manufacture a “primary” purpose that would be permissible to permit PHI to be used or disclosed for a prohibited purpose, particularly because the PHI would lose the protections of the Privacy Rule once it is disclosed to another person, unless that person is also a regulated entity. Another commenter asserted that the proposed rule did not define “primarily” or “mere act,” nor did it provide sufficient examples to provide regulated entities with sufficient information to understand the proposal.

A commenter explained that a request for PHI is often for multiple purposes ***33025** and recommended that the Department revise the proposed Rule of Construction to allow the proposed prohibition to apply where at least one of the purposes for which PHI is sought is to use or disclose the information for a prohibited purpose. Similarly, this commenter recommended the proposed attestation requirement in [45 CFR 164.509\(b\)\(1\)](#) be revised to state that “one of the uses or disclosures” is not prohibited by [45 CFR 164.502\(a\)\(5\)\(iii\)](#).

Response: We agree with the commenter that explained that a request for PHI may be multi-purposed. We also agree with commenters that pointed out that as proposed, the regulatory Rule of Construction appeared to create a secondary standard to consider whether a regulated entity should be prohibited from using or disclosing PHI. As discussed above, the Department is not finalizing a separate Rule of Construction and is not incorporating the phrase “primarily for the purpose of” originally proposed in [45 CFR 164.502\(a\)\(5\)\(iii\)\(D\)](#) into the final prohibition standard. The modified prohibition standard more clearly conveys that it only prohibits the use and disclosure of PHI for the specified purposes when it relates to the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care in certain circumstances.

Comment: Commenters also recommended that the proposed Rule of Construction prohibit health care providers from reporting individuals for the sole reason of having received health care in a state where it was not lawful. They described concerns about the effect of interoperability and data sharing rules that give health care providers ready access to individuals' full medical records and urged the Department to expand the proposed Rule of Construction to mitigate the risks created by the electronic exchange of PHI.

Response: The prohibition, as finalized, is narrowly tailored to operate in a manner that protects the interests of individuals and society in protecting the privacy of PHI while still allowing the use or disclosure of PHI for certain non-health care purposes. We remind regulated entities that they are generally prohibited from disclosing PHI unless there is a specific provision of the Privacy Rule that permits (or, in limited instances, requires) such disclosure. For example, the Privacy Rule permits but does not require regulated entities to disclose PHI about an individual, without the individual's authorization, when such disclosure is required by another law and the disclosure complies with the requirements of the other law.[FN316] The permission to disclose PHI as “required by law” is limited to a “mandate contained in law that compels an entity to use or disclose PHI and that is enforceable in a court of law.” [FN317] Further, where a disclosure is required by law, the disclosure is limited to the relevant requirements of such law.[FN318] Disclosures that do not meet the “required by law” definition of the HIPAA Rules,[FN319] or that exceed what is required by such law,” [FN320] are not permissible disclosures under the required by law permission. Accordingly, regulated entities are prohibited from proactively disclosing PHI under the required by law permission at [45 CFR 164.512\(a\)](#) absent a law requiring mandatory reporting of such PHI.

Comment: A few commenters asserted that the Department should modify the regulatory text of the proposed prohibition to eliminate the need for the proposed Rule of Construction because it is confusing and appears to set forth two different standards.

Response: For the reasons discussed above, we agree and have incorporated the Rule of Construction into the prohibition standard as described above.

Comment: A commenter expressed concerns that beneficial uses or disclosures, such as for conducting investigations into health care fraud, would be too limited and would not address criminal, civil and administrative proceedings, which are not related to receiving, obtaining, facilitating, or providing reproductive health services where the receipt or provision of these services could serve as evidence of another crime.

Response: We disagree with concerns that beneficial uses or disclosures would be too limited under the changes. If PHI is requested for a purpose that is not prohibited and the request complies with the conditions of an applicable permission, including the requirements of the attestation condition are met, where applicable, the regulated entity is permitted to comply with the request.

Comment: Another commenter cited studies to assert that the proposed Rule of Construction would continue to permit health care providers to proactively report on individuals. The commenter also stated that the proposed rule would not clarify how it would interact with mandatory reporting laws that could expose individuals and health care providers to investigations based on the provision of reproductive health care.

Response: The Privacy Rule does not permit a regulated entity to disclose PHI for law enforcement purposes, proactively or otherwise, without an individual's authorization when the disclosure is not made pursuant to process or as otherwise required by law.[FN321] This is true currently and remains true under this final rule.

As discussed above, HIPAA generally preempts state laws requiring the use or disclosure of PHI, except in limited circumstances. Where such mandatory reporting laws are not preempted by HIPAA, regulated entities are limited to disclosing the minimum amount of PHI necessary to comply with the mandatory reporting requirement or the relevant requirements of such law.[FN322]

Comment: Several commenters responded to the question about whether it would be beneficial for the Department to further clarify or provide examples of uses or disclosures of PHI that would be permitted under a final rule. All of these commenters agreed that it would be beneficial for the Department to do so. Of those, several commenters specified that the Department should provide such examples in the final regulatory text. A few commenters who requested examples be provided within the regulatory text also recommended that the language make clear that the examples are illustrative.

Response: The Department declines to include examples of uses or disclosures of PHI that would be permitted in this rule, in regulatory text. We have provided illustrative examples above.

3. Clarifying Personal Representative Status in the Context of Reproductive Health Care

Section 164.502(g) of the Privacy Rule contains the standard for personal ***33026** representatives and generally requires a regulated entity to treat an individual's personal representative as the individual if that person has authority under applicable law (e.g., state law, court order) to act on behalf of the individual in making decisions related to health care.[FN323] For example, the Privacy Rule would treat a legal guardian of an individual who has been declared incompetent by a court as the personal representative of that individual, if consistent with applicable law.[FN324] In this and certain other provisions, the Department seeks to maintain the longstanding balance HIPAA strikes between the interest of a state or other authorities to regulate health and safety and protect vulnerable individuals [FN325] with the goal of maintaining the privacy protections established in the Privacy Rule.[FN326]

In the 2023 Privacy Rule NPRM, the Department expressed concern that some regulated entities may interpret the Privacy Rule as providing them with the ability to refuse to recognize as an individual's personal representative a person who makes reproductive health care decisions, on behalf of the individual, with which the regulated entity disagrees.[FN327] Under these circumstances, current section [45 CFR 164.502\(g\)\(5\)](#) of the Privacy Rule could be interpreted to permit a regulated entity to assert that, by virtue of the personal representative's involvement in the reproductive health care of the individual, the regulated entity believes that the personal representative is subjecting the individual to abuse. Further, this regulated entity might exercise its professional judgment and decide that it is in the best interest of the individual to not recognize the personal representative's authority to make health care decisions for that individual.

To protect the balance of interests struck by the Privacy Rule, the Department proposed to modify [45 CFR 164.502](#) by adding a new paragraph (g)(5)(iii). Proposed [45 CFR 164.502\(g\)\(5\)\(iii\)](#) would ensure that a regulated entity could not deny personal representative status to a person where such status would otherwise be consistent with state and other applicable law primarily because that person provided or facilitated reproductive health care for an individual. The Department expressed its belief that this proposal was narrowly tailored and respected the interests of states and the Department by not unduly interfering with the ability of states to define the nature of the relationship between an individual and another person, including between a minor and a parent, upon whom the state deems it appropriate to bestow personal representative status. The proposal would, however, maintain the existing HIPAA standard by ensuring personal representative status, when otherwise consistent with state law, would not be affected by the type of underlying health care sought.

Several commenters supported the Department's proposal to clarify that the covered entity's reasonable basis for electing not to treat a person as a personal representative of an individual, despite state law or other requirements of the Privacy Rule, cannot be primarily because the person has provided or facilitated reproductive health care. Other commenters expressed concern about their ability to determine what constitutes reproductive health care, as would be required to ascertain whether the covered entity had a reasonable basis to elect not to treat a person as an individual's personal representative. These commenters requested that the Department provide additional clarity in regulatory text or through examples. Other commenters questioned how the Department's proposal would align with existing state law on parental rights.

As discussed throughout this final rule, reproductive health care is uniquely sensitive and must be treated accordingly. Thus, we are finalizing [45 CFR 164.502\(g\)\(5\)](#) with additional modifications as follows. This final rule precludes the denial of personal representative status where the basis of the denial is that the person provided or facilitated reproductive health care instead of the proposed standard that would have precluded denial “primarily” based on these actions. This change clarifies that the covered entity does not have to determine whether the reproductive health care is the “primary” basis for denying a person personal representative status. Additionally, the final rule adds the term “reasonable” before “belief” to align with [45 CFR 164.502\(g\)\(5\)\(i\)\(A\)](#), clarifying that the basis of the covered entity's belief must be reasonable in the circumstances. We are also renumbering paragraphs. Collectively, these changes clarify that it is not reasonable to elect not to treat a person as an individual's personal representative because the person provides or facilitates reproductive health care for and at the request of the individual. The Department is making these changes in response to comments received on the 2023 Privacy Rule NPRM, which are further discussed below.

Comment: Several commenters supported the Department's proposal to clarify that the covered entity's basis for electing not to treat a person as a personal representative of an individual, despite state law or other requirements of the Privacy Rule, cannot be primarily because the person has provided or facilitated reproductive health care.

Response: As explained throughout this final rule, reproductive health care is uniquely sensitive and must be treated as such. Accordingly, we are finalizing this proposal with modifications as described above.

Comment: A commenter expressed concerns that regulated entities would have difficulty determining whether the “primary” basis for the belief that the individual has been or may be subjected to domestic violence, abuse, or neglect by such person, or

that treating such person as the personal representative could endanger the individual related to the provision or facilitation of the reproductive health care, in some circumstances. The commenter requested that the Department provide additional clarity in the regulatory text or through examples.

Response: As discussed above, we have removed the term “primary” before “basis” and reorganized the provision. We believe this change clarifies that the covered entity does not have to determine whether the provision or facilitation of reproductive health care is the “primary” basis for believing that a person who is an individual's personal representative under applicable law has abused, neglected, or endangered the individual, or may do so in the future, such that the covered entity would be permitted to deny the person personal representative status.

Comment: A few commenters requested that the Department clarify that other existing provisions pertaining to personal representatives continue to apply, including the provision that a covered entity should not treat a parent or guardian as a personal representative where state law does not require a minor to obtain parental consent to lawfully obtain health care.

Response: As discussed above, the Privacy Rule generally requires a covered entity to treat a person who, under applicable law, has the authority to act on behalf of an individual in making decisions related to health care *33027 as the individual's personal representative with respect to PHI relevant to such personal representation, with limited exception.[FN328] In this final rule, we are clarifying those limited exceptions apply to this general rule.[FN329] We did not propose, nor are we making any additional changes to the Privacy Rule's provisions on personal representatives. Nothing in this final rule is intended to alter any other use or disclosure permissions for personal representatives, nor does it interfere with the ability of states to define the nature of the relationship between a minor and a parent or guardian.

Comment: A commenter asserted that the proposal could lead to situations in which someone pretending to be a personal representative of the individual would consent to reproductive health care for the individual. According to a few commenters, the proposal would make it easier for a person abusing an individual to obtain access to an individual's PHI because of the limits imposed on the reasonable belief provisions by the proposal. Another commenter asserted that the proposal would hinder state investigations into crimes that affect an individual's reproductive health where such crimes are committed by a person meeting a state's definition of a personal representative.

Response: The Department has no reason to believe, and commenters provided no evidence to suggest, that the final rule will lead to abuse or undermine parental consent. Rather, the final rule will protect sensitive PHI by clarifying that a regulated entity must treat a person as a personal representative of an individual with respect to PHI relevant to such personal representation if such person is, under applicable law, authorized to act on behalf of the individual in making decisions related to health care. This includes a court-appointed guardian, a person with a power of attorney, or other persons with legal authority to make health care decisions. Further, under [45 CFR 164.514\(h\)](#), a covered entity must verify the identity of a person requesting PHI and the authority of any such person to have access to PHI, if the identity is not already known to the covered entity.

Additionally, the final rule allows a covered entity to elect not to treat a person as a personal representative of an individual if the covered entity, in the exercise of professional judgment, has a reasonable belief that the individual has been or may be subjected to domestic violence, abuse, or neglect by such person, or that treating such person as the personal representative could endanger the individual. The final rule only clarifies that the reasonable basis cannot be the provision or facilitation of reproductive health care by the person authorized by applicable law.

Comment: A few commenters recommended that the Department define and interpret personal representative status in the context of reproductive health care consistent with its current interpretation.

Response: We appreciate the comments but decline to specifically define “personal representative” in the context of reproductive health care. We are reducing compliance burdens by eliminating the need for covered entities to determine whether the provision or facilitation of reproductive health care was the “primary” basis for their belief that an individual has been or may be

subjected to domestic violence, abuse, or neglect, or may be endangered by a person authorized by applicable law to act as an individual's personal representative if the covered entity treats the person as such, with respect to PHI relevant to such personal representation.

Comment: A covered entity recommended that the Department set reasonable threshold standards that covered entities would be required to meet if they deny personal representative status to a person because of any legal, social, or professional liability that could attach based on such denials. The commenter further recommended that the Department set objective universal thresholds for denials that are clear, concise, and easily defined.

Response: We appreciate the comment but decline to set a reasonable threshold standard that covered entities would be required to meet if they deny personal representative status to a person. As discussed above, the Department gives covered entities discretion to elect not to treat a person as a personal representative of an individual if the covered entity has a reasonable belief that the individual has been subjected to domestic violence, abuse, or neglect by or would be in danger from a person seeking to act as the personal representative, except where the basis of the denial is that the person provided or facilitated reproductive health care.

Response: As discussed above, a personal representative, with authority under applicable law, stands in the shoes of the individual and has the ability to act for the individual and exercise the individual's rights. Thus, with very limited exceptions, covered entities must provide the personal representative access to the individual's PHI in accordance with [45 CFR 164.524](#) to the extent such information is relevant to such representation.

4. Request for Comments

The Department requested comment on whether to eliminate or narrow any existing permissions to use or disclose “highly sensitive PHI.” [FN330] Most of the comments on this question are discussed in the context of the prohibition.

C. Section 164.509—Uses and Disclosures for Which an Attestation Is Required

1. Current Provision

The Privacy Rule currently separates uses and disclosures into three categories: required, permitted, and prohibited. Permitted uses and disclosures are further subdivided into those to carry out TPO; [FN331] those for which an individual's authorization is required; [FN332] those requiring an opportunity for the individual to agree or object; [FN333] and those for which an authorization or opportunity to agree or object is not required.[FN334] For an individual's authorization to be valid, the Privacy Rule requires that it contain certain specific information to ensure that an individual authorizing a regulated entity to use or disclose their PHI to another person knows and understands to what it is they are agreeing.[FN335]

2. Proposed Rule

As we described in the 2023 Privacy Rule NPRM, a regulated entity presented with a request for PHI would need to discern whether using or disclosing PHI in response to the request would be prohibited. To facilitate compliance with the proposed prohibition at [45 CFR 164.502\(a\)\(5\)\(iii\)](#) while also providing a pathway for regulated entities to disclose PHI for certain permitted purposes, the Department proposed to require that a covered entity obtain an attestation from a person requesting the use or disclosure of PHI in certain circumstances.[FN336]

***33028** Specifically, the Department proposed to add a new section [45 CFR 164.509](#), “Uses and disclosures for which an attestation is required.” This proposed condition would require a regulated entity to obtain certain assurances from the person requesting PHI potentially related to reproductive health care before the PHI is used or disclosed, in the form of a signed and dated written statement attesting that the use or disclosure would not be for a purpose prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#), where the person is making the request under the Privacy Rule permissions at [45 CFR 164.512\(d\)](#) (disclosures for

health oversight activities), (e) (disclosures for judicial and administrative proceedings), (f) (disclosures for law enforcement purposes), or (g)(1) (disclosures about decedents to coroners and medical examiners).

The proposed new section included a description of the proposed attestation contents, including a statement that the use or disclosure is not for a purpose the Department proposed to prohibit as described at [45 CFR 164.502\(a\)\(5\)\(iii\)](#). The 2023 Privacy Rule NPRM also included a discussion about how the Department anticipated the proposed attestation requirement would work in concert with Privacy Rule permissions. Additionally, the proposed attestation provision would also include the general requirements for a valid attestation, and defects of an invalid attestation.[FN337] The Department also proposed to require that an attestation be written in plain language [FN338] and to prohibit it from being “combined with” any other document. Further, the Department's proposal would explicitly permit the attestation to be in an electronic format, as well as electronically signed by the person requesting the disclosure.[FN339] Under the proposal, the attestation would be facially valid when the document meets the required elements of the attestation proposal and includes an electronic signature that is valid under applicable Federal and state law.[FN340]

Additionally, the proposal specified that each use or disclosure request would require a new attestation.

The Department proposed that a regulated entity would be able to rely on the attestation provided that it is objectively reasonable under the circumstances for the regulated entity to believe the statement required by [45 CFR 164.509\(c\)\(1\)\(iv\)](#) that the requested disclosure of PHI is not for a purpose prohibited by [45 CFR 164.502\(a\)\(5\)\(iii\)](#), rather than requiring a regulated entity to investigate the validity of an attestation.[FN341] We explained that it would not be objectively reasonable for a regulated entity to rely on the representation of the person requesting PHI about whether the reproductive health care was provided under circumstances in which it was lawful to provide such health care. This is because we believed that the regulated entity, not the person requesting the disclosure of PHI, has the information about the provision of such health care that is necessary to make this determination. Therefore, we explained that this determination would need to be made by the regulated entity prior to using or disclosing PHI in response to a request for a use or disclosure of PHI that would require an attestation under the proposal.

The attestation proposal also would require a regulated entity to cease use or disclosure of PHI if the regulated entity develops reason to believe, during the course of the use or disclosure, that the representations contained within the attestation were materially incorrect, leading to uses or disclosures for a prohibited purpose.[FN342] Relatedly, the 2023 Privacy Rule NPRM included a discussion of the consequences of material misrepresentations that cause the impermissible use or disclosure of PHI relating to another individual under HIPAA.

To reduce the burden on regulated entities implementing this proposed attestation, the Department requested comment on whether it should develop a model attestation that a regulated entity may use when developing its own attestation templates. The Department did not propose to require that regulated entities use the model attestation.

3. Overview of Public Comments

Most commenters expressed support for the proposal to require an attestation for certain uses and disclosures. Some commenters questioned why the Department did not extend the attestation requirement directly to business associates, consistent with the general prohibition and recommended that the attestation requirements be applied to business associates.

Some of those commenters that supported the proposal to require an attestation expressed concern or made additional recommendations about its components, content, and scope, and the consequences for covered entities that make inadvertent disclosures of PHI without an attestation. A small number of opposing commenters also expressed concerns about the effectiveness and administrative burden of the proposed attestation requirement.

About half of the commenters concerned about the administrative burden of the attestation expressed support for limiting the applicability of the proposed attestation to certain types of uses and disclosures of information, while the other half recommended

expanding the scope of the proposed attestation requirement to mitigate burdens on covered entities or to increase privacy protections for individuals.

Many commenters expressed concern about the Department's statement in the 2023 Privacy Rule NPRM that it would not be objectively reasonable for a regulated entity to rely on the representation of a person requesting the use or disclosure of PHI about whether the PHI sought was related to lawful health care. Specifically, commenters asserted that regulated entities may have difficulties determining whether an attestation is “objectively reasonable” and were unlikely to possess the information necessary to determine the purpose of a person's request for the use or disclosure of PHI.

***33029** Most commenters urged the Department to expand the proposal beyond requests for PHI potentially related to reproductive health care to requests for any PHI because of the associated administrative burden of identifying and segmenting PHI about reproductive health care from other types of PHI. These commenters asserted that the burden would be significant because such PHI can be found throughout the medical record. Commenters also expressed concerns about the ability of EHRs to segment data.

Most commenters recommended that the Department add to or modify the content of the proposed attestation, including to add a statement that the recipient pledges not to redisclose PHI to another party for any of the prohibited purposes or that the request is for the minimum amount of information necessary. Many supported the inclusion of a signed declaration under penalty of perjury and a statement regarding the penalties for perjury to add a layer of accountability.

4. Final Rule

As we explained in the 2023 Privacy Rule NPRM, it may be difficult for regulated entities to distinguish between requests for the use and disclosure of PHI based on whether the request is for a permitted or prohibited purpose, which could lead regulated entities to deny use or disclosure requests for permitted purposes. Additionally, absent an enforcement mechanism, it is likely that persons requesting the use or disclosure of PHI could seek to use Privacy Rule permissions for purposes that are prohibited under the new [45 CFR 164.502\(a\)\(5\)\(iii\)](#). Accordingly, the Department is finalizing the proposed attestation requirement, with modification, as described below. We intend to publish a model attestation prior to the compliance date for this final rule.

First, the Department is renumbering the attestation provision such that the requirement is now [45 CFR 164.509\(a\)\(1\)](#) and modifying that requirement to hold business associates directly liable for compliance with the attestation requirement. This change was made to address concerns raised by commenters who questioned why the Department did not extend the attestation requirement directly to business associates, consistent with the general prohibition and with revisions made to the HIPAA Rules in the 2013 Omnibus Rule, as required by the HITECH Act. The Department has authority to take enforcement action against business associates only for requirements for which the business associate is directly liable.[FN343] Thus, under the proposed attestation requirement, a business associate would only have been required to comply with the proposed [45 CFR 164.509](#) if such obligation was explicitly included within its business associate agreement.[FN344]

Both covered entities and business associates process requests for PHI. The Privacy Rule permits regulated entities to determine whether a business associate can respond to such requests or whether they are required to defer to the covered entity.[FN345] As noted by commenters, while many PHI requests processed by a business associate pursuant to [45 CFR 164.512\(d\)-\(g\)\(1\)](#) are processed on behalf of the covered entity, persons may elect to request PHI directly from the business associate. Thus, the Department has determined that it is appropriate to hold both covered entities and business associates directly liable for compliance with the attestation requirement. Expanding the attestation requirement to apply to business associates will ensure that the business associate is directly liable for compliance with it, regardless of whether compliance with [45 CFR 164.509](#) is explicitly included in a BAA.

The Department is also adopting the proposed attestation requirement that a regulated entity obtain an attestation only for PHI “potentially related to reproductive health care.” As discussed in the 2023 Privacy Rule NPRM, this will limit the number of requests that require an attestation, and therefore, the burden of the attestation requirement on regulated entities

and persons requesting PHI. The Department reminds regulated entities that they are permitted, but not required, to respond to law enforcement requests for PHI where the purpose of the request is not one for which regulated entities are prohibited from disclosing PHI. By narrowing the scope of the attestation to PHI “potentially related to reproductive health care,” the attestation requirement will not unnecessarily interfere with or delay law enforcement investigations that do not involve PHI “potentially related to reproductive health care.” While in practice this scope may be wide, we believe the privacy interests of individuals who have obtained reproductive health care necessitates the inclusion of “potentially related” PHI. We are concerned that extending the attestation requirement to all PHI could unnecessarily delay law enforcement investigations that are not for a purpose prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#). We acknowledge commenters' concerns about the ability of regulated entities to operationalize the attestation condition and note that the requirement to obtain an attestation applies where the request is for PHI “potentially related to reproductive health care,” as opposed to PHI “related to reproductive health care.” Consistent with the Department's instructions to regulated entities since the Privacy Rule's inception, we have taken a flexible approach to allow scalability based on a regulated entity's activities and size. All regulated entities must take appropriate steps to address privacy concerns. Regulated entities should weigh the costs and benefits of alternative approaches when determining the scope and extent of their compliance activities, including when developing policies and procedures to comply with the Privacy Rule.[FN346] The Department will assess the progress of regulated entities' compliance with this requirement and promulgate guidance as appropriate. The Department also notes that with limited exceptions, the Privacy Rule generally permits but does not require the use or disclosure of PHI when the conditions set by the Privacy Rule for the specific use or disclosure of PHI are met.

The Department is adopting the proposed requirement that an attestation be obtained where a request is made under the Privacy Rule permissions at [45 CFR 164.512\(d\)](#) (disclosures for health oversight activities), (e) (disclosures for judicial and administrative proceedings), (f) (disclosures for law enforcement purposes), or (g)(1) (disclosures about decedents to coroners and medical examiners). This requirement will help ensure that these Privacy Rule permissions cannot be used to circumvent the new prohibition at [45 *33030 CFR 164.502\(a\)\(5\)\(iii\)](#) and continue permitting essential disclosures, while also limiting the attestation's burden on regulated entities by providing a standard mechanism by which the regulated entity can ascertain whether a requested use or disclosure is prohibited under this final rule. The attestation requirement is intended to reduce the burden of determining whether the PHI request is for a purpose prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#), but it does not absolve regulated entities of the responsibility of making this determination, nor does it absolve regulated entities of the responsibility for ensuring that such requests meet the other conditions of the relevant permission.

We are modifying the proposal by revising [45 CFR 164.509\(a\)\(1\)](#) to clarify that a regulated entity may not use or disclose PHI where the use or disclosure does not meet all of the Privacy Rule's applicable conditions, including the attestation requirement. While this is consistent with the existing requirements of the Privacy Rule, we determined that it was necessary to reiterate this requirement here based on comments we received. Thus, when this final rule is read holistically, a regulated entity is not permitted to use or disclose PHI where such disclosure does not meet all of the Privacy Rule's applicable conditions, including the attestation requirement.

We are also modifying the proposal by adding [45 CFR 164.509\(a\)\(2\)](#) to clarify that the use or disclosure of PHI based on a defective attestation does not meet the attestation requirement. For example, the attestation requirement would not be met if a regulated entity relies on an attestation where it is not reasonable to do so because the attestation would be defective under [45 CFR 164.509\(b\)\(2\)\(v\)](#). Accordingly, it would be a violation of the Privacy Rule if the regulated entity makes a use or disclosure in response to a defective attestation.

The Department is modifying the proposal to prohibit inclusion in the attestation of any elements that are not specifically required by [45 CFR 164.509\(c\)](#). This provision addresses concerns that regulated entities might require persons requesting PHI to provide information beyond that which is required under [45 CFR 164.509\(c\)](#). Such additional requirements could make it burdensome for persons requesting PHI to submit a valid attestation when they make a request pursuant to [45 CFR 164.512\(d\)](#), (e), (f), or (g)(1). Additionally, a person requesting PHI is not required to use the specific attestation form provided by a regulated entity, as long as the attestation provided by such person is compliant with the requirements of [45 CFR 164.509](#).

Additionally, the Department is modifying the proposed prohibition on compound attestations. Specifically, the final rule prohibits the attestation from being “combined with” any other document. The modification clarifies that while an attestation may not be combined with other “forms,” additional documentation to support the information provided in the attestation may be submitted. This additional documentation may not replace or substitute for any of the attestation's required elements. The attestation itself must be clearly labeled, distinct from any surrounding text, and completed in its entirety, but documentation to support the statement at [45 CFR 164.509\(c\)\(1\)\(iv\)](#) or to overcome the presumption at [45 CFR 164.502\(a\)\(5\)\(iii\)\(C\)](#) may be appended to the attestation. Thus, a regulated entity must ensure that the required elements of the attestation are met, and should review any additional documents provided by the person making the request when making the required determinations.

A regulated entity may use this information—the information on the attestation combined with any additional documentation provided by the person making the request for PHI—to make a reasonable determination that the attestation is true, consistent with [45 CFR 164.509\(b\)\(2\)\(v\)](#). For example, an attestation would not be impermissibly “combined with” a subpoena if it is attached to it, provided that the attestation is clearly labeled as such. As another example, an electronic attestation would not be impermissibly “combined with” another document where the attestation is on the same screen as the other document, provided that the attestation is clearly and distinctly labeled as such.

The Department is finalizing the proposed content requirements with modifications as follows. Specifically, the Department is finalizing the proposal that an attestation must include that the person requesting the disclosure confirm the types of PHI that they are requesting; clearly identify the name of the individual whose PHI is being requested, if practicable, or if not practicable, the class of individuals whose PHI is being requested; and confirm, in writing, that the use or disclosure is not for a purpose prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#). For purposes of the “class of individuals” described in [45 CFR 164.509\(c\)\(1\)\(i\)\(B\)](#), the Department clarifies that the requesting entity may describe such a class in general terms—for example, as all individuals who were treated by a certain health care provider or for whom a certain health care provider submitted claims, all individuals who received a certain procedure, or all individuals with given health insurance coverage.

As we proposed, we are finalizing a requirement that the attestation include a clear statement that the use or disclosure is not for a purpose prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#). This requirement may be satisfied with a series of checkboxes that identifies why the use or disclosure is not prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#) (i.e., the use or disclosure is not for a purpose specified in [45 CFR 164.502\(a\)\(5\)\(iii\)\(A\)](#); or the use or disclosure is for a purpose that would be prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)\(A\)](#), but the reproductive health care at issue was not lawful under the circumstances in which it was provided so the Rule of Applicability is not satisfied, and thus the prohibition does not apply).

The Department is adding another new required element, a statement that the attestation is signed with the understanding that a person who knowingly and in violation of HIPAA obtains or discloses IIHI relating to another individual, or discloses IIHI to another person, may be subject to criminal liability.[FN347] We believe that adding this language satisfies the intent that led us to consider including a penalty of perjury requirement and with applicable law. The statement does not impose new liability on persons who sign an attestation; instead, including the statement in the attestation ensures that persons who request the use or disclosure of PHI for which an attestation is required are on notice of and acknowledge the consequences of making such requests under false pretenses.

The Department is also finalizing the proposed requirement that the attestation must be written in plain language. Additionally, the Department is finalizing its proposal to permit the attestation to be in electronic format and for it to be electronically signed by the person requesting the disclosure where such electronic signature is valid under applicable law.[FN348] The Department declines to mandate a specific electronic format for the attestation.

As we proposed, an attestation will be limited to the specific use or disclosure. Accordingly, each use or disclosure ***33031** request for PHI will require a new attestation.

There is no exception to the minimum necessary standard for uses and disclosures made pursuant to an attestation under [45 CFR 164.509](#).^[FN349] Thus, a regulated entity will have to limit a use or disclosure to the minimum necessary when provided in response to a request that would be subject to the proposed attestation requirement, unless one of the specified exceptions to the minimum necessary standard in [45 CFR 164.502\(b\)\(2\)](#) applies. Where the person requesting the PHI is also a regulated entity, that person will also need to make reasonable efforts to limit their request to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.^[FN350]

The Department is not requiring a regulated entity to investigate the validity of an attestation provided by a person requesting a use or disclosure of PHI. Rather, a regulated entity is generally permitted to rely on the attestation if, under the circumstances, a regulated entity reasonably determines that the request is not for investigating or imposing liability for the mere act of seeking, obtaining, providing, or facilitating allegedly unlawful reproductive health care. In addition, a regulated entity is generally permitted to rely on the attestation and any accompanying material if, under the circumstances, a regulated entity reasonably could conclude (e.g., upon examination of adequate supporting documentation provided by the person making the request) that the requested disclosure of PHI is not for a purpose prohibited by [45 CFR 164.502\(a\)\(5\)\(iii\)](#), consistent with the approach taken in the Privacy Rule ^[FN351] and elsewhere in this final rule. If such reliance is not reasonable, then the regulated entity may not rely on the attestation. This is a change from the proposed language, which permitted reliance based on an “objectively reasonable” standard. The proposed standard was modified because a reasonable person standard is inherently objective.^[FN352] Thus, including “objectively” in the description of the standard was redundant.

For requests involving allegedly unlawful reproductive health care, the extent to which a regulated entity may reasonably rely on an attestation depends in part on whether the regulated entity provided the reproductive health care at issue. Under the final rule, it would not be reasonable for a regulated entity to rely on the representation made by a person requesting the use or disclosure of PHI that the reproductive health care was unlawful under the circumstances in which it was provided unless such representation meets the conditions set forth in the presumption at [45 CFR 164.502\(a\)\(5\)\(iii\)\(C\)](#). As discussed above, under the presumption, reproductive health care is presumed to be lawful under the circumstances in which such health care is provided unless a regulated entity has actual knowledge, or information from the person making the request that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided. Where the reproductive health care at issue was provided by a person other than the regulated entity receiving the request for the use or disclosure of PHI and the presumption is overcome, the regulated entity is permitted to use or disclose PHI in response to the request upon receipt of an attestation where it is reasonable to rely on the representations made in the attestation. It is not reasonable for the regulated entity to rely solely on a statement of the person requesting the use or disclosure of PHI that the reproductive health care was unlawful under the circumstances in which such health care was provided. Instead, the person requesting the use or disclosure of PHI must provide the regulated entity with information such that it would constitute actual knowledge or that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided. A regulated entity that receives a request for PHI involving reproductive health care provided by that regulated entity should review the relevant PHI in its possession and other related information (e.g., license of health care provider that provided the health care, operating license for the facility in which such health care was provided) to determine whether the reproductive health care was lawful under the circumstances in which it was provided prior to using or disclosing PHI in response to a request for PHI that requires an attestation. Where the request is about reproductive health care that is provided by the regulated entity receiving the request, it would not be reasonable for a regulated entity to automatically rely on a representation made by a person requesting the use or disclosure of PHI about whether the reproductive health care was provided under the circumstances in which it was lawful to provide such health care. Rather, the regulated entity must review the individual's PHI to consider the circumstances under which it provided the reproductive health care to determine whether such reliance is reasonable. Therefore, where the request involves the use or disclosure of PHI potentially related to reproductive health care that was provided by the recipient of the request, the regulated entity must make the determination about whether it provided the health care lawfully prior to using or disclosing PHI in response to a request that requires an attestation.

For example, if a law enforcement official requested PHI potentially related to reproductive health care to investigate a person for the mere act of seeking, obtaining, providing or facilitating allegedly unlawful reproductive health care, it would not be reasonable for a regulated entity that receives such a request to rely solely on a signed attestation that states that the reproductive health care was not lawful under the circumstances in which it was provided, as set forth in 45 CFR 164.502(a)(5)(iii)(B), and therefore, that the requested disclosure is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii)(A). This is regardless of whether the regulated entity receiving the request for PHI provided the reproductive health care at issue. Assuming that the attestation is not facially deficient, a regulated entity must consider the totality of the circumstances surrounding the attestation and whether it is reasonable to rely on the attestation in those circumstances. To determine whether it is reasonable to rely on the attestation, a regulated entity should consider, among other things: who is requesting the use or disclosure of PHI; the permission upon which the person making the request is relying; the *33032 information provided to satisfy other conditions of the relevant permission; the PHI requested and its relationship to the stated purpose of the request; and, where the reproductive health care was supplied by another person, whether the regulated entity has: (1) actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided; or (2) factual information supplied by the person requesting the use or disclosure of PHI that would demonstrate to a reasonable regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided.

For example, a regulated entity receives an attestation from a Federal law enforcement official, along with a court ordered warrant demanding PHI potentially related to reproductive health care. The law enforcement official represents that the request is about reproductive health care that was not lawful under the circumstances in which such health care was provided, but the official will not divulge more information because they allege that doing so would jeopardize an ongoing criminal investigation. In this example, if the regulated entity itself provided the reproductive health care and, based on the information in its possession, reasonably determines that such health care was lawful under the circumstances in which it was provided, the regulated entity may not disclose the requested PHI.

If the regulated entity did not provide the reproductive health care, it may not disclose the requested PHI absent additional factual information because the official requesting the PHI has not provided sufficient information to overcome the presumption at 45 CFR 164.502(a)(5)(iii)(C). Further, it also would not be reasonable under the circumstances for the regulated entity to rely on the attestation that the information would not be used for a purpose prohibited by 45 CFR 164.502(a)(5)(iii) because of the presumption that the reproductive health care was lawfully provided.

However, in cases where the presumption of lawfulness applies, the regulated entity would be permitted to make the disclosure, for example, where the law enforcement official provides additional factual information for the regulated entity to determine that there is a substantial factual basis that the reproductive health care was not lawful under the circumstances in which such health care was provided. As another example, a regulated entity could rebut the presumption of lawfulness by relying on a sworn statement by a law enforcement official that the PHI is necessary for an investigation into violations of specific criminal codes unrelated to the provision of reproductive health care (e.g., billing fraud) or an affidavit from an individual that the individual obtained unlawful reproductive health care from a different health care provider and the requested PHI is relevant to that investigation. Similarly, if a regulated entity receives an attestation from a Federal law enforcement official, along with a court-ordered warrant demanding PHI potentially related to reproductive health care, that both specify that the purpose of the request is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii), the regulated entity may rely on the attestation and warrant, subject to the requirements of 45 CFR 164.512(f)(1)(ii)(A).

Lastly, this final rule requires a regulated entity to cease use or disclosure of PHI if the regulated entity, during the course of the use or disclosure, discovers information reasonably showing that the representations contained within the attestation are materially incorrect, leading to uses or disclosures for a prohibited purpose.[FN353] As we explained in the 2023 Privacy Rule NPRM, pursuant to HIPAA, a person who knowingly and in violation of the Administrative Simplification provisions obtains or discloses IIHI relating to another individual or discloses IIHI to another person would be subject to criminal liability. [FN354] Thus, a person who knowingly and in violation of HIPAA [FN355] falsifies an attestation (e.g., makes material misrepresentations about the intended uses of the PHI requested) to obtain (or cause to be disclosed) an individual's IIHI could

be subject to criminal penalties as outlined in the statute.[FN356] Additionally, a disclosure made based on an attestation that contains material misrepresentations after the regulated entity becomes aware of such misrepresentations constitutes an impermissible disclosure, which requires notifications of a breach to the individual, the Secretary, and in some cases, the media. [FN357]

The attestation requirement does not replace the conditions of the Privacy Rule's permissions for a regulated entity to disclose PHI, including in response to a subpoena, discovery request, or other lawful process, or administrative request. Instead, the attestation is designed to work with the permissions and their requirements. If PHI is disclosed pursuant to 45 CFR 164.512(e)(1)(ii) or (f)(1)(ii)(C), a regulated entity will need to verify that the requirements of each provision are met, in addition to satisfying the requirements of the new attestation provision under 45 CFR 164.509. Furthermore, the requirements of 45 CFR 164.528, the right to an accounting of disclosures of PHI made by a covered entity, are not affected by the attestation requirement. Thus, disclosures made pursuant to a permission under 45 CFR 164.512(d), (e), (f), or (g) must be included in the accounting, including when they are made pursuant to an attestation.

5. Responses to Public Comments

Comment: Most commenters supported the proposal to require an attestation for certain uses and disclosures. A few commenters recognized the benefits of the attestation requirement, despite the potential increase in administrative burden for regulated entities.

Many commenters opposed the proposal for what they described as administrative burden, questionable effectiveness, and lack of clarity. A few commenters stated that the requirements imposed an inappropriate compliance burden on covered entities that would need to determine whether a PHI request was “potentially related” to sensitive personal health care, and, along with a health care provider who otherwise supported the attestation, they recommended instead that the Department impose requirements on the person requesting the use or disclosure of PHI. Many commenters expressed concerns about the ability of covered entities to operationalize the proposed requirement with the limitation to PHI potentially related to reproductive health care because it would require the ability to segment PHI, which the Department previously acknowledged is generally unavailable. A few commenters questioned the effectiveness of the proposed attestation *33033 requirement, as compared to its potential burden, enforceability, and effects on access to maternal and specialty health care.

Response: We agree with commenters that the attestation requirement will bolster the privacy of PHI and acknowledge that implementation of this important safeguard requires additional administrative activities by regulated entities. The Department considered removing the limitation on the application of the attestation condition to PHI “potentially related to reproductive health care,” but we are concerned that expanding it to apply to all requests for PHI made for specified purposes would impose even more burden on regulated entities. The requirement is to determine whether the requested PHI is “potentially related to reproductive health care,” not whether it is “related to reproductive health care.” Thus, regulated entities are not required to make an affirmative determination that the requested PHI is in fact related to reproductive health care before requiring a person requesting PHI to provide an attestation. We note that the focus of the attestation requirement has been limited to PHI potentially related to reproductive health care because the changes to the legal landscape have heightened privacy concerns about reproductive health care that is lawful under the circumstances in which such health care is provided. We also note that the provision of an attestation itself is not determinant of whether the request is for a prohibited purpose. Rather, regulated entities must consider whether a request for PHI is for a prohibited purpose, regardless of whether the request is made for a purpose for which the Privacy Rule requires an attestation.

The Department is limited to applying the HIPAA Rules to those entities covered by HIPAA (i.e., health plans, health care clearinghouses, and health care providers that conduct covered transactions) and to business associates, as provided under the HITECH Act. Accordingly, the Department is limited to imposing obligations on persons requesting the use or disclosure of PHI to those who are also regulated entities.

The attestation condition has been drafted to promote the privacy of information about lawful reproductive health care, including maternal and specialty health care, while still permitting certain uses of PHI. Regulated entities, including covered entities that specialize in providing reproductive health care may determine, based on their assessment of what PHI is potentially related to reproductive health care, that an attestation must accompany all requests they receive for the use or disclosure of any PHI made pursuant to and in compliance with 45 CFR 164.512(d)-(g)(1). Further, the attestation requirement only applies to the specified requests for PHI and should not affect any intake of new patients or provision of maternal health care.

The Department is not requiring a regulated entity to investigate the veracity of the information provided in support of an attestation because doing so would impose a significant administrative burden on regulated entities and persons requesting the use or disclosure of PHI without proportional benefit. Additionally, requiring such an investigation by the regulated entity may cause unnecessary delays to law enforcement activities. Rather, the Department is finalizing a regulated entity's ability to rely on the attestation provided that it is reasonable under the circumstances for the regulated entity to believe the statement required by 45 CFR 164.509(c)(1)(iv) that the requested disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii). If such reliance is not reasonable, then the regulated entity may not rely on the attestation.

A regulated entity that receives a request for PHI potentially related to reproductive health care for purposes specified in 45 CFR 164.512(d), (e), (f), or (g)(1) may accept information, in addition to the attestation, from the person requesting the PHI to support its ability to make the determinations required by 45 CFR 164.502(a)(5)(iii) and 45 CFR 164.509(b)(v).

For example, it likely would not be reasonable for a regulated entity to rely on an attestation from a public official who represents that their request is for a purpose that is not prohibited, if the request for PHI is overly broad for its purported purpose and the public official has publicly stated that they will be investigating health care providers for providing reproductive health care. In such cases, regulated entities should consider the circumstances surrounding an attestation to determine whether they can reasonably rely on the attestation. Although we have modified the regulatory text by removing “objectively,” the standard remains unchanged in practice because a reasonableness standard is an objective standard. As we also discussed above, it is not reasonable for a regulated entity that provided the reproductive health care at issue to rely on a representation made by a person requesting the use or disclosure of PHI that the reproductive health care at issue was unlawful under the circumstance in which such health care was provided. A regulated entity that makes a disclosure where it was not reasonable to rely on the representation made by the person requesting the use or disclosure may be subject to enforcement action by OCR.

Additionally, as discussed in greater detail above, a person who knowingly and in violation of the Administrative Simplification provisions obtains or discloses IIHI relating to another individual or discloses IIHI to another person would be subject to criminal liability.[FN358] We believe that this provision serves as a deterrent for those who otherwise might request PHI in violation of this final rule. It also will continue to permit essential disclosures while ensuring that Privacy Rule permissions cannot be used to circumvent the new prohibition, thereby enhancing the privacy of individuals' PHI and protecting other important interests.

Comment: Several commenters opposed the attestation proposal because they believed that the proposal would make it more difficult for law enforcement to request PHI and for entities to respond to such requests, potentially putting them in situations where they need to choose between complying with a court order and impermissibly disclosing PHI. A few individuals stated that the proposal would have a chilling effect on the ability of a state to conduct investigations or proceedings for which the use or disclosure of PHI could be beneficial, particularly in cases involving rape, incest, sex trafficking, domestic violence, abuse, and neglect.

Response: We acknowledge that the attestation provision may require regulated entities to obtain additional information from persons requesting PHI in certain circumstances. As discussed above, this condition is consistent with the operation of the Privacy Rule since its inception, which has always required regulated entities to obtain additional information from persons requesting PHI in certain circumstances, such as where the use or disclosure is one for which an authorization or opportunity to agree or object is not required.[FN359] However, as also discussed above, any burden the attestation may impose on persons requesting PHI is outweighed by the privacy interests that this final rule is designed to protect.

A person requesting PHI pursuant to [45 CFR 164.512\(d\)-\(g\)\(1\)](#) may elect to provide an attestation with their request, even if a determination has not ***33034** yet been made concerning whether such request is for PHI potentially related to reproductive health care. Similarly, the Privacy Rule does not require a regulated entity to respond to requests for PHI.

Comment: Some commenters were concerned about the effect of the attestation requirement on the electronic exchange of PHI and recommended approaches for incorporating attestations into a HIE environment. A commenter expressed concern that the requirement for an attestation would delay or prevent automated data exchange using Fast Healthcare Interoperability Resources® (FHIR®) APIs and might impede innovation. They requested guidance on how to implement the attestation condition in an HIE environment without impeding regulated exchanges or industry innovations using extensive data exchange via FHIR APIs. Commenters also recommended that the Department issue guidance on implementing attestation policies in circumstances not required by this rule that would not constitute information blocking. A commenter encouraged the Department to implement processes that limit the liability of health care providers for the actions of third parties. For example, the commenter requested that the Department clarify that a refusal to disclose PHI absent an attestation is protected from a finding of information blocking.

Response: We do not believe that this final rule prevents the disclosure of PHI via a HIE. We disagree that this requirement prevents the exchange of data using FHIR APIs under these permissions or for automated health data exchange more broadly. PHI can be disclosed as requested if the regulated entity obtains a valid attestation and the request meets the conditions of an applicable permission. The attestation requirement does not affect any requests via FHIR API that fall outside of the [45 CFR 164.512\(d\)-\(g\)\(1\)](#) permissions. For example, a disclosure of PHI from a covered health care provider to another health care provider for care coordination purposes would not require an attestation because the disclosure would not be for a purpose addressed by [45 CFR 164.512\(d\)-\(g\)\(1\)](#). The importance of ensuring the protection of an individual's interests in the privacy of their PHI and society in improving the effectiveness of the health care system far outweigh any potential administrative burdens or delays in the electronic exchange of PHI for non-health care purposes. Further, compliance with applicable law does not constitute information blocking.[FN360] Thus, we do not believe additional regulatory language is necessary at this time. OCR regularly collaborates with other Federal agencies, including ONC, to develop guidance on compliance with Federal standards and to address questions that arise about the ability of regulated entities to comply with applicable laws.

The permissions for which the Department is requiring that a regulated entity obtain an attestation prior to using or disclosing PHI are already conditioned upon meeting certain requirements, which generally require manual review. The Department acknowledges that certain persons may need to adjust their workflows to account for the attestation requirement. While there may be some delays until new processes are implemented, any disruptions will decrease over time. Thus, we do not anticipate that this final rule will contribute to additional delays in the disclosure of PHI.

The Department is finalizing a new regulatory presumption that permits a regulated entity to presume reproductive health care provided by another person was lawful unless the regulated entity has actual knowledge or factual information supplied by the person requesting the use or disclosure of PHI that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided. This presumption will facilitate the determination by the regulated entity about whether a request for the use or disclosure of PHI would be subject to the prohibition, and thus will reduce the risk of an impermissible use or disclosure of the requested PHI, thereby reducing the liability of regulated entities that receive requests for PHI to which the prohibition may apply, but where they did not provide the reproductive health care at issue.

Comment: Many commenters questioned the Department's rationale for not extending the attestation requirement directly to business associates, consistent with the general prohibition. Some commenters recommended that the attestation requirement be applied to business associates because persons requesting the use or disclosure of PHI may directly approach a business associate for this PHI (and the business associate agreement may permit such disclosures or be silent regarding whether the business

associate may respond to them). Commenters also requested clarification of the responsibilities of business associates with respect to attestations and questioned whether the proposal would require amendment of their business associate agreements.

Response: As discussed above, we agree with the commenters that the attestation requirement should apply directly to business associates because they receive direct requests for PHI and are subject to the general prohibition in the same manner as covered entities. Therefore, we are modifying 45 CFR 164.509 to ensure that it expressly applies to both covered entities and their business associates.

Comment: Although a few commenters expressed support for limiting the attestation condition to requests regarding “PHI potentially related to reproductive health care,” many commenters recommended that the proposed requirement to obtain an attestation be broadly applied to requests for any PHI. Many stated that it would be easier and more efficient for regulated entities if all requests related to a prohibited purpose required the attestation, regardless of the PHI being requested. According to these commenters, this would allow the regulated entity to avoid making any determinations regarding the PHI. A few explained that expanding the requirement to all PHI would appropriately place the burden of demonstrating that the requested disclosure was permissible on the person making request.

Several commenters asserted that information related to reproductive health care is potentially found in every department, record, and system, including those that may not have a readily apparent relationship to reproductive health care. As a result, according to these commenters, it would be onerous and costly to separate different types of health information in a medical record. According to other commenters, the volume of records requests received by health systems would render any requirement on a health care provider to redact PHI from an individual's medical record in the absence of an attestation overly burdensome and increase the risk of unauthorized disclosure. Some *33035 commenters explained that staff managing health information generally do not have the legal or medical training to determine whether a PHI request may be for PHI potentially related to reproductive health care, particularly given the breadth of most requests (e.g., for all medical records of an entity, of a particular health care provider or a particular individual). These commenters also raised concerns that the lack of legal or medical training could lead to inconsistent application of the rule, the inadvertent disclosure of PHI potentially related to reproductive health care, or delay the use or disclosure of PHI, even when the individual has not sought or obtained reproductive health care. Many commenters asserted that determining whether a request for the use or disclosure of PHI includes PHI potentially related to reproductive health care is difficult and a significant burden on health information professionals, particularly where the covered entity did not provide or facilitate the health care. According to some commenters, some business associates, such as cloud services providers, may not have the ability to determine whether the PHI that they maintain includes PHI potentially related to reproductive health care.

Some commenters posited that the result of this requirement would be that health care providers would refuse to provide any PHI in response to a request for the use or disclosure PHI on any matter that could possibly be construed as potentially related to reproductive health care. They and others stated that limiting the proposed prohibition to one category of PHI would require regulated entities to label or segment certain PHI within medical records, which would be impractical and costly because EHRs are unable to reliably segregate or flag PHI retrospectively.

Response: We acknowledge the comments from regulated entities that expressed concerns about the effects of the limitation of the attestation requirement to PHI potentially related to reproductive health care. However, the Department is concerned that extending the attestation requirement to all PHI could result in unintended consequences, such as the potential delay of law enforcement investigations that do not require PHI potentially related to reproductive health care. By contrast, an attestation requirement is necessary for PHI potentially related to reproductive health care because of recent changes to the legal landscape that make it more likely that PHI will be sought for punitive non-health care purposes, and thus more likely to be subject to disclosure by regulated entities if the requested disclosure is permissible under the Privacy Rule, thereby harming the interests that HIPAA seeks to protect. Accordingly, the Department is not modifying the attestation requirement that a regulated entity obtain an attestation only for PHI potentially related to reproductive health care.

The Department acknowledges that the attestation requirement may increase the burden on regulated entities, but we disagree that regulated entities are unable to make the required assessments of attestations. Regulated entities currently conduct similar assessments when determining whether PHI may be disclosed to a personal representative, when making disclosures that are required by law or for public health purposes, and for various other permitted purposes. Regulated entities also regularly review medical records to comply with minimum necessary requirements. The Department is cognizant that an expanded attestation requirement could significantly increase burden if it were to expand this requirement to all disclosures in the absence of the sensitivities described in this final rule.

Comment: Many commenters supported the proposal to limit the requirement to obtain an attestation with a request for uses and disclosures for certain permissions, namely that have the greatest potential to be connected with a purpose for which the Department proposed to prohibit the use and disclosure of PHI. Some commenters expressed their belief that the Department had identified the appropriate permissions for which the attestation would provide additional safeguards.

Many commenters suggested modifications, primarily expansions or clarifications of the types of permitted uses and disclosures that would be subject to the attestation. Generally, commenters explained their belief that their recommended modifications would either mitigate the burden of the requirement to ascertain the purposes of the requested disclosure or increase privacy protections for individuals.

Commenters recommended multiple ways to expand the attestation requirement, such as extending it to all permissions in [45 CFR 164.512](#); disclosures required by law, for public health activities, and to avert a serious threat to health or safety; disclosures for treatment purposes to a person not regulated by HIPAA or disclosures to any person who might use the PHI for a prohibited purpose; and any disclosure at the discretion of the covered entity.

Response: The Department declines to expand the permissions for which an attestation is required at this time. The Department specifically chose to limit the attestation condition to the permissions at [45 CFR 164.512\(d\)-\(g\)\(1\)](#) because these permissions have the greatest potential to result in the use or disclosure of an individual's PHI for a purpose prohibited at [45 CFR 164.502\(a\)\(5\)\(iii\)](#). In the context of other permissions, where the risk of improper use or disclosure is less, the benefits of an attestation condition would be outweighed by the administrative burden of compliance. Accordingly, any disclosures made pursuant to [45 CFR 164.512\(b\)](#), which includes disclosures for public health surveillance, investigations, or interventions, do not require an attestation. However, we note that requests made pursuant to other permissions of the rule remain subject to and must be evaluated for compliance with the prohibition at [45 CFR 164.502\(a\)\(5\)\(iii\)](#).

Comment: A commenter stated that no attestation should be needed for judicial and administrative proceedings because current requirements are adequate. Instead, the commenter requested that the Department consider expanding procedural protections.

Response: We are finalizing the requirement that regulated entities obtain an attestation as a condition of a use or disclosure of PHI for judicial and administrative proceedings. As previously discussed, the attestation requirement ensures that certain Privacy Rule permissions are not used to circumvent the prohibition. The attestation requirement also reduces the burden on regulated entities because it is specifically designed to facilitate compliance with the prohibition under [45 CFR 164.502\(a\)\(5\)\(iii\)](#) by helping regulated entities determine whether the use or disclosure of the requested PHI is permitted. Although a court order, qualified protective order, satisfactory assurance, or subpoena may have a restriction that prevents information requested from being further disclosed, it protects PHI only after it has been used or disclosed. Thus, the regulated entity's use or disclosure of PHI could still violate the prohibition at [45 CFR 164.502\(a\)\(5\)\(iii\)](#), even if that disclosure is made in response to a court order, qualified protective order, satisfactory assurance, or subpoena. The attestation requirement helps to mitigate the risk of violations in these circumstances.

Comment: A few commenters expressed concerns about their ability to implement the attestation requirement ***33036** in circumstances where the use or disclosure is triggered by a mandatory reporting law or verbal request and recommended that no attestation should be required in any case where disclosure of PHI is required by law. According to the commenters, an

attestation requirement could require a significant change to operational workflows for permitted disclosures and significantly impede operations for state and local agencies that conduct death investigations and perform public health studies and initiatives.

Response: The Privacy Rule at [45 CFR 164.512\(a\)](#) permits certain uses and disclosures of PHI that are required by law, including notification of certain deaths by a covered health care provider to a medical examiner, when those uses and disclosures are limited to the requirements of such law. The attestation condition does not apply to the mandatory disclosures made pursuant to [45 CFR 164.512\(a\)](#). Other mandatory reporting that is subject to [45 CFR 164.512\(a\)\(2\)](#) has always been subject to the additional requirements of [45 CFR 164.512\(c\)](#), [\(e\)](#), or [\(f\)](#). Further, mandatory reporting for public health activities pursuant to [45 CFR 164.512\(b\)](#) do not require an attestation.

The attestation condition applies if the regulated entity is making a use or disclosure to a coroner or medical examiner pursuant to [45 CFR 164.512\(g\)\(1\)](#). We understand that this may require regulated entities to adjust their workflows to comply with this requirement. For example, regulated entities could consider having an electronic attestation form readily available for persons that request the use or disclosure of PHI potentially related to reproductive health care because doing so may reduce delays in the regulated entity's response time related to the attestation condition. Thus, this condition will not significantly impede operations for persons who request information because the interruptions will decrease as they adjust their workflows to accommodate the new condition.

We remind regulated entities that the prohibition in [45 CFR 164.502\(a\)\(5\)\(iii\)](#) applies, regardless of whether the request for PHI is made pursuant to a permission for which an attestation is required or another permission.

Comment: Many commenters urged the Department to implement a reasonable, good faith standard or a safe harbor for situations in which a regulated entity discloses PHI and the person requesting the PHI either uses or rediscloses it for a purpose that would be prohibited under the proposed rule. Some commenters were concerned that a covered entity will be liable for inadvertent disclosures of PHI and sought the benefit of the affirmative defense afforded at [45 CFR 160.410\(b\)\(2\)](#).

Response: The Department declines to add a “good faith” standard or safe harbor to this final rule. As discussed above, the Department is not finalizing a separate Rule of Construction and is not incorporating the phrase “primarily for the purpose of” into the final prohibition standard.

As we explained in the 2023 Privacy Rule NPRM, [45 CFR 164.509](#) requires a new attestation for each use or disclosure request; a single attestation would not be sufficient to permit multiple uses or disclosures. This requirement is unlike the authorization, where generally, when a regulated entity receives a valid authorization, they may continue to use or disclose PHI to the person requesting the use or disclosure of PHI pursuant to that authorization after the initial disclosure, provided that such subsequent uses and disclosures are valid and related to that authorization. We understand that this may constitute an additional administrative burden for both the regulated entity and the person or entity requesting the information; however, requiring an attestation for each use or disclosure is necessary to ensure that certain Privacy Rule permissions are not used to circumvent the new prohibition at [45 CFR 164.502\(a\)\(5\)\(iii\)](#), and to permit essential disclosures.

Comment: Some commenters expressed support for permitting a regulated entity to rely on an attestation if “it appears objectively reasonable” or “when objectively reasonable” and not requiring covered entities to investigate the accuracy of an attestation, thereby mitigating liability to the regulated entity, if not fully protecting an individual. Many commenters expressed concern that it would not be objectively reasonable for a regulated entity to rely on a representation made by the person requesting the use or disclosure of PHI that the PHI sought was related to unlawful health care. The commenters requested a guarantee that a health care provider's reliance on a “facially valid” attestation would be objectively reasonable without requiring the entity to investigate the intentions of the person requesting the use or disclosure of PHI and the validity of their attestation. A commenter recommended that the final rule direct regulated entities to take attestations at face value and hold harmless regulated entities in the event of a false attestation.

Commenters offered several reasons for these recommendations, including the burden on covered entities where they are required to determine: (1) the veracity of every attestation; (2) whether an attestation is required; and (3) whether the statement that the request for the use or disclosure is not for a purpose prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#) is objectively reasonable.

Response: To assist in effectuating the prohibition, this Final Rule requires an attestation in some circumstances. We recognize the potential burden on regulated entities to investigate the validity of every attestation and do not require that they conduct a full investigation in each instance. However, as discussed above, if an attestation, on its face, meets the requirements at [45 CFR 164.509\(c\)](#), a regulated entity must consider the totality of the circumstances surrounding the attestation and whether it is reasonable to rely on the attestation in those circumstances. To determine whether it is reasonable to rely on the attestation, a regulated entity should consider, among other things: who is requesting the use or disclosure of PHI; the permission upon which the person making the request is relying; the information provided to satisfy other conditions of the relevant permission; the PHI requested and its relationship to the purpose of the request (i.e., does the request meet the minimum necessary standard in relation to the purpose of the request); and, where the presumption at [45 CFR 164.502\(a\)\(5\)\(iii\)\(C\)](#) applies, information provided by the person requesting the use or disclosure of PHI to overcome that presumption.

For example, as discussed above, it may not be reasonable for a regulated entity to rely on an attestation filed by a public official that a request for PHI potentially related to reproductive health care is not for a prohibited purpose when that public official has publicly stated their interest in investigating or imposing liability on those who seek, obtain, provide, or facilitate certain types of lawful reproductive health care. If a regulated entity concludes that it would not be reasonable to rely on the attestation in this instance, the regulated entity would be prohibited from disclosing the requested PHI unless and until the public official provided additional information that enables the regulated entity to assess the veracity of its attestation. In contrast, it may be reasonable to rely on the representation of a public official that a request for PHI potentially related to reproductive ***33037** health care is not for a prohibited purpose if the stated purpose for the request is to investigate insurance fraud and the public official making the request is expressly authorized by law to conduct insurance fraud investigations as part of their legal mandate. Therefore, as discussed above, the Department is balancing these considerations by finalizing language that generally permits a regulated entity to rely on the attestation if it is reasonable for the regulated entity to believe the statement that the requested disclosure of PHI is not for a purpose prohibited by [45 CFR 164.502\(a\)\(5\)\(iii\)](#).^[FN361] To further assist regulated entities in determining whether it is reasonable to rely on the attestation, the requirement that the attestation include a clear statement that the use or disclosure is not for a prohibited purpose under [45 CFR 164.502\(a\)\(5\)\(iii\)](#) may be satisfied with a statement that identifies why the use or disclosure is not prohibited, which could be checkboxes that indicate that the use or disclosure is not for a purpose described in [45 CFR 164.502\(a\)\(5\)\(iii\)\(A\)](#), or that the reproductive health care does not satisfy the Rule of Applicability at [45 CFR 164.502\(a\)\(5\)\(iii\)\(B\)](#).

Where the request for the use or disclosure of PHI is made of the regulated entity that provided the reproductive health care at issue, the regulated entity should ensure that the reproductive health care was not lawful under the circumstances in which such health care was provided before using or disclosing the requested PHI. If the reproductive health care at issue was provided under circumstances in which such health care was lawful, the regulated entity must obtain an attestation and determine whether it is reasonable to rely on the attestation that the use or disclosure is not being requested to conduct an investigation into or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating such reproductive health care. If the reproductive health care at issue was provided under circumstances in which such health care was unlawful, the regulated entity is permitted, but not required, to disclose the PHI if the disclosure meets the conditions of an applicable Privacy Rule permission, which may include an attestation.

Regulated entities will not generally be held liable for disclosing PHI to a person who signed the attestation under false pretenses, provided that the requirements of [45 CFR 164.509](#) are met, and it is reasonable under the circumstances for the regulated entity to believe the statement that the requested disclosure of PHI is not for a purpose prohibited by [45 CFR 164.502\(a\)\(5\)\(iii\)](#).

Comment: A commenter recommended that the rule clarify the relationship between the attestation and 45 CFR 164.514(h) regarding verification requirements. They requested that the Department consider making explicit in the Final Rule that reliance on legal process would not be appropriate in the absence of an attestation.

Response: The verification requirement under 45 CFR 164.514(h) [FN362] is separate from the attestation requirement, and a regulated entity must still comply with 45 CFR 164.514(h) when processing an attestation. The final rule makes clear that the attestation requirement will apply if the request for PHI potentially related to reproductive health care is made pursuant to permissions under 45 CFR 164.512(d)-(g)(1), which may include disclosing PHI pursuant to a legal process.

Comment: Some commenters stated that it is difficult to determine the purpose of a request for the use or disclosure of PHI because many requests include only a general purpose. A commenter asserted that staff would need to screen all incoming requests, a task that may require legal or clinical expertise. Further, some commenters stated that regulated entities may experience conflict with persons requesting the use or disclosure of PHI about signing the form.

Response: This final rule prohibits the use and disclosure of PHI for certain purposes and conditions disclosures for certain purposes upon the receipt of an attestation. Thus, it is incumbent upon the regulated entity receiving the request to determine whether disclosure is in compliance with the Privacy Rule. To help the regulated entity make such a determination, the Department is adding to the required elements of the attestation a description of the purpose of the request that is sufficient for the regulated entity to determine whether the prohibition at 45 CFR 164.502(a)(5)(iii) may apply to the request. Requests for the use or disclosure of PHI for the specified purposes are likely subject to heightened scrutiny by the regulated entity currently because of other conditions imposed upon such disclosures by the Privacy Rule, so additional expertise will not always be required when processing a request for the use or disclosure of PHI and the accompanying attestation. For example, under the Privacy Rule, a regulated entity must determine whether a request for the use or disclosure of PHI for a judicial or administrative proceeding made using a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal contains “satisfactory assurances” that reasonable efforts have been made by the person making the request either: (1) to ensure that the individual who is the subject of the PHI that has been requested has been given notice of the request; [FN363] or (2) to secure a qualified protective order that meets certain requirements specified in the Privacy Rule.[FN364] The Privacy Rule further details how regulated entities are to determine whether they have received “satisfactory assurances” for both options described above.[FN365] Such requirements ensure that a regulated entity must already carefully review requests for such purposes, such that the attestation condition likely poses minimal additional burden for such requests. In any event, the Department believes that these administrative burdens are outweighed by the privacy interests that this final rule seeks to protect.

Comment: Many commenters asserted that it would be reasonable to require affirmative verification under penalty of perjury that the request for the use or disclosure of PHI is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii) because it would signal an intent to penalize requests *33038 made to contravene the prohibition; would incentivize persons requesting the use or disclosure of PHI to consider whether their request is for a purpose prohibited under 45 CFR 164.502(a)(5)(iii); deter unlawful “fishing expeditions” or conceal improper intent; and add a layer of accountability. Another commenter stated this heightened standard would enable the covered entity to reasonably rely in good faith on the substance of the attestation without further investigation, delay, cost, burden, or dispute. According to the commenter, a person making a request for the use or disclosure of PHI in good faith should have minimal to no concern when providing a statement signed under penalty of perjury. Another commenter supported a requirement that a person requesting the use or disclosure of PHI provide an affirmative verification made under penalty of perjury that the use or disclosure is not for purpose prohibited under 45 CFR 164.502(a)(5)(iii) because it would suggest that evidence obtained falsely would not be admissible in a legal proceeding. A commenter asserted that it is important to ensure that the proposed attestations would be as effective as possible, and including a signed declaration made under penalty of perjury is critical to ensuring their effectiveness in the current legal environment. A commenter endorsed adding a statement regarding perjury to the proposed attestation because it would place the person requesting the use or disclosure of PHI on notice of the criminal penalties if the person were to violate the proposed requirement.

A commenter asserted that the penalty of perjury requirement is a common signature standard for legal and administrative proceedings and expressed support for expanding it to other proceedings. The commenter also expressed support for considering other options because of concerns that the application and consequences of making a statement under a penalty of perjury may lack clarity outside of certain proceedings.

Response: We appreciate commenters' suggestions; however, the Department ultimately decided that the addition of a penalty of perjury would be unnecessary in light of the statutory criminal and civil penalties under HIPAA. 42 U.S.C. 1320d-6 provides that any person who knowingly and in violation of the Administrative Simplification provisions obtains IIHI relating to another individual or discloses IIHI to another person is subject to criminal liability.[FN366] A regulated entity is also subject to civil penalties for violations of requirements of the HIPAA Rules.[FN367] Thus, a person that requests PHI who knowingly falsifies an attestation (e.g., makes material misrepresentations as to the intended uses of the PHI requested) to obtain PHI or cause PHI to be disclosed would be in violation of HIPAA and could be subject to criminal penalties.[FN368]

Comment: Some commenters expressed support for requiring that the attestation include a statement that a person signing an attestation is doing so under penalty of perjury, but they also questioned its ability to prevent a person from requesting the use or disclosure of PHI for a purpose prohibited under 45 CFR 164.502(a)(5)(iii) and recommended additional requirements or alternatives. One commenter expressed concern that there would be no disincentive for the recipient to submit an attestation signed under false pretenses in the absence of enforceable penalties. A different commenter questioned the efficacy of a penalty of perjury requirement because the person requesting the use or disclosure may not be the person that uses the PHI for a purpose prohibited under 45 CFR 164.502(a)(5)(iii); it might be another person who uses the information for a purpose prohibited under that provision. According to the commenter, no criminal or other penalty would attach because that other person did not sign the attestation. The commenter also expressed concern that an attestation signed on behalf of an entity may not be enforceable because the person who signed the attestation did not have authority to bind the entity.

Commenters variously recommended that the Department include language that the person requesting the use or disclosure of PHI would not further use or disclose the PHI for a purpose prohibited under 45 CFR 164.502(a)(5)(iii) and that the requested information is the minimum necessary, or require a search warrant or data use agreement instead of an attestation. A commenter recommended that the Department provide individuals with an actionable remedy, such as the right to receive a portion of any civil money penalty assessed to the regulated entity or the right to "claw back" the disclosure from the receiving entity if the party that signed the attestation later violates its terms.

Response: The Department understands and shares commenters' concerns about redisclosures that would be prohibited by this rule if the disclosure was made by a regulated entity. However, HIPAA limits the Department's authority to regulating PHI maintained or transmitted by a regulated entity, that is a covered entity or their business associate. Accordingly, a person that is not a regulated entity generally may use or disclose such information without further limitation by the HIPAA Rules.

Requiring search warrants or data use agreements as a condition of the use or disclosure of PHI is beyond the scope of this final rule.

With respect to the commenter's concern about situations in which a person who does not have the appropriate authority requests PHI on behalf of a public official, the Privacy Rule generally requires that a regulated entity verify the identity and legal authority of persons requesting PHI prior to making the disclosure.[FN369] Where a disclosure of PHI is to a public official or person acting on behalf of a public official who has the authority to request the information, a regulated entity may verify the authority of that public official by relying on, if reliance is reasonable under the circumstances, either a written statement of legal authority under which the information is requested (or an oral statement, if the written statement is impracticable).[FN370] Alternatively, a regulated entity may presume the public official's legal authority if a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or judicial administrative tribunal.[FN371] We remind regulated entities that a determination that a public official has the authority to make a request for the use or disclosure does not mean that the Privacy Rule permits them to obtain any and all information that the official requests. In such circumstances,

the regulated entity should carefully review the conditions of the applicable permission to ensure that they are met. Where the condition involves a warrant, subpoena, or similar instrument, the regulated entity must also review the scope of the authority granted by the warrant, subpoena, or order to determine the extent of the PHI that it is permitted to disclose.[FN372] Further, a regulated entity may rely, if such reliance is reasonable under the *33039 circumstances, on a requested disclosure by a public official as the minimum necessary if the public official represents that the requested PHI is the minimum necessary for the stated purpose.[FN373]

HIPAA specifies the remedies available to the Federal Government where persons violate the statute's Administrative Simplification provisions: civil monetary penalties [FN374] and criminal fines and imprisonment.[FN375] HIPAA does not include a private right of action.

Comment: One commenter asked the Department to clarify that anyone providing a false attestation would be held accountable for false statements with appropriate or significant civil fines or criminal penalties for the material misrepresentation. Another commenter specifically recommended that the Department consider it a material misrepresentation for a person to sign an attestation without an objectively reasonable basis to suspect that the reproductive health care of interest was unlawful under the circumstances in which such health care was provided. The commenter asserted that the attestation should include specific language that any person who is requesting the use or disclosure of PHI because they believe the reproductive health care was not lawful under the circumstances in which such health care was provided must have a reasonable basis for that belief (e.g., a statement from a witness) and that the absence of an articulable, fact-based reasonable suspicion would constitute a material misrepresentation. According to the commenter, such a requirement would prevent fishing expeditions because persons requesting the use or disclosure of PHI would be required to have an actual, objective reason for believing that a person provided health care in violation of state or Federal law.

Response: The Department agrees that it would be a material misrepresentation if a person who signs an attestation does not have an objectively reasonable basis to suspect that the reproductive health care was provided under circumstances in which it was unlawful, and that an objectively reasonable basis of suspicion requires specific and articulable facts associated with the individual whose PHI is requested and the health care they received. We decline to include a statement of this position on the attestation because it is encompassed in the language that requires persons making a request for PHI to attest that they are not making the request for a prohibited purpose and the language ensuring that persons making such requests are aware of the potential liability for knowingly and in violation of HIPAA obtaining IIHI relating to an individual or disclosing IIHI to another person.

Comment: Some commenters urged the Department to include additional provisions to monitor and enforce the attestation condition, including requiring that a court order, written attestation, or valid authorization accompany requests for the use or disclosure of PHI for legal or administrative proceedings or law enforcement investigations.

Response: The attestation condition does not replace the conditions of the Privacy Rule's permissions for a regulated entity to disclose PHI in response to a subpoena, discovery request, or other lawful process,[FN376] or administrative request.[FN377] Instead, it is designed to work with these permissions and associated condition. For PHI to be disclosed pursuant to [45 CFR 164.512\(e\)\(1\)\(ii\)](#) and [\(f\)\(1\)\(ii\)\(C\)](#), a regulated entity must verify that the relevant conditions are met and also satisfy the attestation condition at [45 CFR 164.509](#). We do not believe it is necessary to include additional requirements to monitor and enforce implementation of the attestation condition because a person who knowingly and in violation of the Administrative Simplification provisions obtains or discloses IIHI relating to another individual or discloses IIHI to another person would be subject to criminal liability.[FN378]

Comment: Almost all commenters responding to the Department's request for comment expressed support for a Department-developed model attestation or sample language that could be used by regulated entities to reduce the implementation burden of the attestation condition. A large health care provider expressed appreciation for options that would simplify the process for reviewing requests for the use or disclosure of PHI made pursuant to [45 CFR 164.512\(d\)-\(g\)\(1\)](#). Other commenters asserted

that a standard form would reduce unnecessary variation, support a consistent approach, decrease implementation costs, and make it easier for a regulated entity to identify requests for the use or disclosure of PHI for purposes prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#).

Several commenters suggested that a universal or standardized attestation form would reduce the burden of the attestation requirement, especially for smaller health care providers, and reduce delays in the disclosure of PHI resulting from the need for legal review or unfamiliarity with the format of an attestation provided by a person requesting the use or disclosure of PHI. One of these commenters stated this would also support electronic data exchange by standardizing attestation fields and the format. Most commenters expressed opposition to a Department-required format and recommended that the Department permit covered entities to modify the language of the attestation.

Some commenters requested that the model attestation include a plain language explanation and a tip sheet or guidance for completion. They also requested that the model be an electronic, fillable form with a clear heading and that the editing capabilities be limited to the specific required fields. Some commenters recommended that the model attestation contain an outline of penalties for misuse of PHI.

A commenter requested that the Department guarantee that a health care provider's good faith reliance on a model attestation form would be objectively reasonable.

Response: We appreciate these recommendations and intend to publish model attestation language before the compliance date of this final rule. As discussed above, if an attestation, on its face, meets the requirements at [45 CFR 164.509\(c\)](#), a regulated entity must consider the totality of the circumstances surrounding the attestation and whether it is reasonable to rely on the attestation in those circumstances.

Comment: In response to the Department's request for comment on how the proposed attestation would affect a regulated entity's process for responding to regular or routine requests from certain persons, a few commenters explained their current workflows and the resource requirements for managing these requests.

Some commenters suggested that an attestation requirement might require changes to workflows and discussed the changes that might be made.

Response: The Department appreciates these insights into how regulated entities currently respond to certain requests for the use or disclosure of PHI. We confirm that a person requesting the use or disclosure of PHI ***33040** pursuant to [45 CFR 164.512\(d\)](#), [\(e\)](#), [\(f\)](#), or [\(g\)\(1\)](#) must provide the regulated entity a signed and truthful attestation where the request is for PHI potentially related to reproductive health care before the regulated entity is permitted to use or disclose the requested PHI. The Department will consider developing guidance and technical assistance as needed on these topics in the future as necessary to ensure compliance with the Privacy Rule, including both the prohibition at [45 CFR 164.502\(a\)\(5\)\(iii\)](#) and [164.509](#). It may benefit a regulated entity to require such documentation where the requested use or disclosure is for TPO or in response to a valid authorization or individual right of access request.

Comment: A few commenters recommended imposing obligations to limit redisclosures of PHI for certain purposes.

A few commenters stated that a person requesting the use or disclosure of PHI could seek a court order or provide a written attestation to permit the regulated entity to make the disclosure in question in the event they were unable to obtain an authorization.

Response: While we understand commenters' concerns regarding the uses and disclosures of health information by entities not covered by the Privacy Rule, the Department is limited to applying the HIPAA Rules to those entities covered by HIPAA (i.e.,

health plans, health care clearinghouses, and health care providers that conduct covered transactions) and to business associates, as provided under the HITECH Act.

In the 2023 Privacy Rule NPRM, the Department considered permitting regulated entities to make uses or disclosures of PHI only after obtaining a valid authorization. However, the Department rejected the approach because requiring an authorization in all circumstances would not reflect the appropriate balance between individual privacy interests and other societal interests in disclosure. In particular, individuals may decline to authorize disclosure of PHI even in circumstances where their privacy interests are reduced and societal interests in disclosure are heightened, such as where the reproductive health care was unlawful under the circumstances in which it was provided.

Comment: Some commenters requested that the Department provide educational resources for regulated entities to implement the attestation. A commenter encouraged the Department to strongly enforce the attestation provision.

Response: We appreciate these recommendations and commit to providing additional resources to assist regulated entities with implementation of this rule.

Comment: In response to the Department's request for comment on alternative documentation that could assist regulated entities in complying with the proposed limitations on the use and disclosure of PHI, some commenters recommended that an attestation always be required, even if additional documentation is mandated, because the attestation would place the person requesting the use or disclosure of PHI on notice of the prohibition and to hold them accountable if they use the PHI for a purpose prohibited by 45 CFR 164.502(a)(5)(iii), in addition to helping a covered entity to determine whether the PHI is being requested for a legitimate or prohibited purpose. Others agreed because of the risk of coercion when authorizations are sought from individuals for certain purposes.

Some commenters suggested that the Department require that a court order, written attestation, or valid authorization accompany a request for the use or disclosure of any PHI for legal or administrative proceedings or law enforcement investigations because there are circumstances under which it would be unlikely for a person to obtain an authorization. Some commenters recommended that the Department not require an attestation when the disclosure of PHI is required by law, or when so ordered by a court of competent jurisdiction. A commenter proposed that the Department permit regulated entities to make the specified uses and disclosures with a written attestation, a HIPAA authorization, or alternative documentation described by the Department, including a court order, to minimize the administrative burden.

Response: The Department appreciates the approaches recommended by commenters to ensure that PHI requested is not for a prohibited purpose. We also believe that the attestation will place the person requesting the use or disclosure of PHI on notice of the prohibition and serve to hold them accountable if they use the PHI for a purpose prohibited by 45 CFR 164.502(a)(5)(iii). However, we have limited the attestation requirement to requests for PHI that is potentially related to reproductive health care. In addition, as discussed above, because the Privacy Rule's authorization requirements empower individuals to make decisions about who has access to their PHI, we are not adopting the proposed exception to the permission to use or disclose PHI pursuant to a valid authorization, nor are we adopting the other recommendations made by commenters. The Department is not finalizing its proposal to prohibit the disclosure of PHI for a purpose prohibited by 45 CFR 164.502(a)(5)(iii) pursuant to an authorization. Accordingly, the final rule permits the disclosure of an individual's PHI to another person pursuant to a valid authorization, even if the disclosure would otherwise be prohibited under this rule. Therefore, a regulated entity may disclose PHI for a purpose that otherwise would be prohibited under 45 CFR 164.502(a)(5)(iii) by obtaining a valid authorization or pursuant to the individual right of access. We reiterate that in all cases, the conditions of the underlying permission must be met before a regulated entity is permitted to use or disclose the requested PHI.

D. Section 164.512—Uses and Disclosures for Which an Authorization or Opportunity To Agree or Object Is Not Required

1. Applying the Prohibition and Attestation Condition to Certain Permitted Uses and Disclosures

Section 164.512 of the Privacy Rule contains the standards for uses and disclosures for which an authorization or opportunity to agree or object is not required. Many of the uses and disclosures addressed by 45 CFR 164.512 relate to government or administrative functions and are described in the 2000 Privacy Rule preamble as “national priority purposes.” [FN379] These permissions for uses and disclosures were not required by HIPAA; instead they represented the Secretary's previous balancing of the privacy interests and expectations of individuals and the interests of communities in making certain information available for community purposes, such as for certain public health, health care oversight, and research purposes.[FN380] As discussed previously, the Department, in its implementation of HIPAA, has sought to ensure that individuals do not forgo health care when needed—or withhold important information from their health care providers that may affect the quality of health care they receive—out of a fear that their sensitive information would be revealed outside of their relationships with their health care providers.

To clarify that the proposal at 45 CFR 164.502(a)(5)(iii) would prohibit the use and disclosure of PHI in some *33041 circumstances where such uses or disclosures are currently permitted, the Department proposed to cite the proposed prohibition at the beginning of the introductory text of 45 CFR 164.512 and condition certain disclosures on the receipt of the attestation proposed at 45 CFR 164.509.[FN381] The proposed modification would add the clause, “Except as provided by 45 CFR 164.502(a)(5)(iii), [. . .]” and add “and 45 CFR 164.509” to “subject to the applicable requirements of this section.” This would create a new requirement to obtain an attestation from the person requesting the use and disclosure of PHI as a condition of making certain types of permitted uses and disclosures of PHI. Thus, under the proposal and subject to the Department finalizing the prohibition at paragraph (a)(5)(iii) of 45 CFR 164.502, uses and disclosures of PHI for certain purposes would be prohibited unless a regulated entity first obtained an attestation from the person requesting the use and disclosure under proposed 45 CFR 164.509.

The Department also proposed to replace “orally” with “verbally” at the end of the introductory paragraph for clarity.

Overview of Public Comments

While many commenters addressed the proposals to add a prohibition on the use and disclosure of PHI and to require an attestation in certain circumstances, few commenters addressed the proposal to modify the introductory paragraph to 45 CFR 164.512. Such commenters either expressed support for it or requested additional guidance on the Department's intention or the proposal's operation.

The Department is adopting its proposal without modification. As discussed above, this change creates a new requirement for a regulated entity to obtain an attestation from a person requesting the use or disclosure of PHI as a condition of making certain types of permitted uses and disclosures of PHI. For example, the Privacy Rule currently permits uses and disclosures for health care oversight,[FN382] judicial and administrative proceedings,[FN383] law enforcement purposes,[FN384] and about decedents to coroners and medical examiners,[FN385] provided specified conditions are met. When read in conjunction with the new prohibition at 45 CFR 164.502(a)(5)(iii), uses and disclosures of PHI for these purposes will be subject to an additional condition that the regulated entity first obtain an attestation from the person requesting the use and disclosure under the new attestation requirement at 45 CFR 164.509.

The Department assumes that there will be instances in which state or other law requires a regulated entity to use or disclose PHI for health care oversight, judicial and administrative proceedings, law enforcement purposes, or about decedents to coroners and medical examiners for a purpose not related to one of the prohibited purposes in 45 CFR 164.502(a)(5)(iii). The Department believes that a regulated entity will be able to comply with such laws and the attestation requirement. For example, a regulated entity may continue to disclose PHI without an individual's authorization to a state medical board, a prosecutor, or a coroner, in accordance with the Privacy Rule, when the request is accompanied by the required attestation. As a result, a regulated entity generally may continue to assist the state in carrying out its health care oversight, judicial and administrative functions, law enforcement, and coroner duties with the use or disclosure of PHI once a facially valid attestation has been provided to the regulated entity from whom PHI is sought. However, where an attestation is required but not obtained, a state seeking information about an individual's reproductive health or reproductive health care would need to obtain such information from

an entity not regulated under the Privacy Rule [FN386] or demonstrate that the regulated entity has actual knowledge that the reproductive health care was not lawful under the circumstances in which such health care was provided, thereby reversing the presumption described at [45 CFR 164.502\(a\)\(5\)\(iii\)\(C\)](#).

Additionally, we are replacing “orally” with “verbally” for clarity. No substantive change is intended.

Comment: One commenter expressed support for the Department's proposed revision to [45 CFR 164.512](#), while another commenter requested additional examples or detail in preamble about what the Department intends by this revision.

Response: The Department intends that the uses and disclosures of PHI made in accordance with [45 CFR 164.512](#) would be subject to both the [45 CFR 164.502\(a\)\(5\)\(iii\)](#) prohibition and the [45 CFR 164.509](#) attestation, when applicable, specifically uses or disclosures made for health oversight activities,[FN387] judicial and administrative proceedings,[FN388] law enforcement purposes,[FN389] and about decedents to coroners and medical examiners.[FN390] For example, a regulated entity may disclose PHI for law enforcement purposes, subject to the conditions of the permission at [45 CFR 164.512\(f\)](#), where the purpose of the request for the use or disclosure is to investigate a sexual assault and the person requesting the PHI provides the regulated entity with a valid attestation signifying that the purpose of the request is not for a prohibited purpose. Similarly, where a request meets the requirements of [45 CFR 164.502\(a\)\(5\)\(iii\)](#), a regulated entity may disclose PHI for law enforcement purposes, subject to the conditions of the permission at [45 CFR 164.512\(f\)](#), where the purpose of the request for the use or disclosure is to investigate the unlawful provision of reproductive health care with a valid attestation signifying that the purpose of the request is not one that is prohibited (i.e., that the purpose of the use or disclosure is not to investigate or impose liability on any person for the lawful provision of reproductive health care). As another example, a regulated entity may disclose PHI to a state Medicaid agency in accordance with [45 CFR 164.512\(d\)](#) where the purpose of the request is to ensure that the regulated entity is providing the reproductive health care for which the regulated entity has submitted claims for payment to Medicaid after obtaining an attestation that meets the requirements of [45 CFR 164.509](#) from the state Medicaid agency.

Comment: One commenter requested clarification regarding the intersection between the Department's proposed Rule of Construction at [45 CFR 164.502\(a\)\(5\)\(iii\)\(D\)](#) and its proposal at [45 CFR 164.512](#).

Response: The Department is not adopting the proposed Rule of Construction. Rather, the language of the proposal has been integrated into the prohibition standard at [45 CFR 164.502\(a\)\(5\)\(iii\)\(A\)](#). The finalized prohibition standard requires a ***33042** regulated entity to ensure that they obtain a valid attestation from a person requesting the use or disclosure of PHI for health oversight activities, judicial and administrative proceedings, law enforcement purposes, or about decedents to coroners or medical examiners, assuring the regulated entity that the purpose of the request is not for a purpose prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#).

2. Making a Technical Correction to the Heading of [45 CFR 164.512\(c\)](#) and Clarifying That Providing or Facilitating Reproductive Health Care Is Not Abuse, Neglect, or Domestic Violence

Paragraph (c) of [45 CFR 164.512](#) permits a regulated entity to disclose PHI, under specified conditions, to an authorized government agency where the regulated entity reasonably believes the individual is a victim of abuse, neglect, or domestic violence. The regulatory text includes a serial comma, which clearly indicates that the provision addresses victims of three different types of crimes, but the heading of this standard does not include the serial comma.

For grammatical clarity, the Department proposed to add the serial comma after the word “neglect” in the heading of the standard contained at [45 CFR 164.512\(c\)](#). [FN391]

The Department also proposed to add a new paragraph (c)(3) to [45 CFR 164.512\(c\)](#), with the heading “Rule of construction,” to clarify that the permission to use or disclose PHI in reports of abuse, neglect, or domestic violence does not permit uses or disclosures based primarily on the provision or facilitation of reproductive health care to the individual. [FN392] The Department intended the proposed provision to safeguard the privacy of individuals' PHI against claims that uses and disclosures of that PHI

are warranted because the provision or facilitation of reproductive health care, in and of itself, may constitute abuse, neglect, or domestic violence.

A few commenters supported the proposal because it would clarify that providing or facilitating access to health care is not itself abuse, neglect, or violence, while others expressed opposition to the proposal because they believed it would prevent health care providers from reporting abuse based on the provision of reproductive health care, including potentially coerced reproductive health care. Commenters both supported and opposed the inclusion of the phrase “based primarily.”

The Department is finalizing the proposal to add the serial comma after the word “neglect” in the heading of the standard contained at [45 CFR 164.512\(c\)](#).

As we explained in the 2023 Privacy Rule NPRM, the Department is concerned that recent state actions may lead regulated entities to believe that they are permitted to make disclosures of PHI when they believe that persons who provide or facilitate access to reproductive health care are perpetrators of a crime simply because they provide or facilitate access to reproductive health care. Thus, the Department is clarifying that providing or facilitating access to lawful reproductive health care itself is not abuse, neglect, or domestic violence for purposes of the Privacy Rule. This is consistent with the Department's understanding that the provision or facilitation of lawful health care is not itself abuse, neglect, or domestic violence. Such clarification has not previously been required, but recent developments in the legal landscape have made it necessary for us to codify this interpretation in the context of reproductive health care.

Accordingly, the Department is finalizing the proposed Rule of Construction at [45 CFR 164.512\(c\)\(3\)](#), with modification as follows. The modification clarifies the circumstances under which regulated entities that are mandatory reporters of abuse, neglect, or domestic violence are permitted to make such reports. Specifically, we are replacing “based primarily on” with language specifying that the prohibition at [45 CFR 164.502\(a\)\(5\)\(iii\)](#) cannot be circumvented by the permission to use or disclose PHI to report abuse, neglect, or domestic violence where the “sole basis of” the report is the provision or facilitation of reproductive health care. Thus, the Department makes clear that it may be reasonable for a covered entity that is a mandatory reporter to believe that an individual is the victim of abuse, neglect, or domestic violence and to make such report to the government authority authorized by law to receive such reports in circumstances where the provision of reproductive health care to the individual is but one factor prompting the suspicion. For example, it would not be reasonable for a covered entity to believe that an individual is the victim of domestic violence solely because the individual's spouse facilitated the covered entity's provision of reproductive health care to the individual.

Comment: A few commenters supported the Department's proposal. One commenter asserted that providing or facilitating access to any type of health care is not in and of itself abuse, neglect, or domestic violence and urged the Department to expand the scope of this language, particularly if the prohibition is similarly expanded in the final rule.

Response: The Department appreciates the comments about the modifications to [45 CFR 164.512\(c\)](#). As discussed above, the scope of the prohibition is limited to reproductive health care. The proposed and final regulations are narrowly tailored and limited in scope to not increase regulatory burden beyond appropriate public policy objectives. Thus, we decline to expand the scope of this provision, as well.

Comment: A large coalition expressed concerns about mandatory domestic violence and sexual assault reporting laws. According to the coalition, mandatory reporting laws reduce the willingness of domestic violence survivors to seek help, including health care, and that the reports themselves worsen the situation for most survivors. The coalition asserted that permitting the disclosure of PHI to law enforcement and other agencies for reports of abuse, neglect, or domestic violence isolates survivors of such abuse and puts them at risk of losing their children. These commenters recommended that the Department prevent such disclosures.

Some commenters expressed opposition to the proposal because they believe it would put victims of domestic abuse at risk because it would prevent health care providers from reporting abuse, including child abuse, based on the provision or facilitation of reproductive health care. A commenter asserted that the proposal would circumvent the exception prohibiting disclosures to abusive persons at [45 CFR 164.512\(b\)\(1\)\(ii\)](#). According to another commenter, the change would chill the willingness of covered entities to cooperate with investigations and judicial proceedings concerning individuals who may have used reproductive health care, regardless of the matter being adjudicated.

According to another commenter, the proposal is aimed at undermining state laws and shielding persons who provide or facilitate reproductive health care. Commenters expressed concern that the proposal would prohibit reports of abuse, neglect, or domestic violence because such reports are made for the purpose of investigating or prosecuting a person for providing or facilitating *33043 unlawful reproductive health care, and for committing sexual assault.

Response: The Department appreciates the concerns raised by the commenters. Since publication of the final Privacy Rule in 2000, the Department has acknowledged that covered entities, including covered health care providers, may have legal obligations to report PHI in certain circumstances, including about suspected victims of abuse, neglect, or domestic violence. The Department did not propose to modify the Privacy Rule's permission to disclose PHI at [45 CFR 164.512\(c\)](#). The Department declines to expand its proposal to eliminate the permission for covered entities to disclose PHI to public health authorities, law enforcement, and other government authority authorized by law to receive reports of abuse, neglect, or domestic violence.

Additionally, the Department does not agree that covered entities will be prevented from reporting PHI about victims of abuse, neglect, or domestic violence. The new language at [45 CFR 164.512\(c\)\(3\)](#) is narrowly tailored to reduce the conflation between lawfully provided reproductive health care and the view that such lawful health care, on its own, is abuse. Readers are referred to the preamble discussion of [45 CFR 164.502\(a\)\(5\)\(iii\)](#) that describes the scope of disclosure changes which are being made applicable to [45 CFR 164.512\(c\)](#).

The Department does not agree that the modifications circumvent the exception prohibiting disclosures to abusive persons at [45 CFR 164.512\(b\)\(1\)\(ii\)](#). The new language at [45 CFR 164.512\(c\)\(3\)](#) does not modify or change the current Privacy Rule provision for disclosures to a public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect. We believe the commenter is referring to [45 CFR 164.512\(c\)\(2\)](#), which requires a covered entity to inform an individual that a report has been or will be made, and [45 CFR 164.512\(c\)\(2\)\(ii\)](#), which removes the requirement to inform the individual when the covered entity would be informing a personal representative and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment. Because the new language at [45 CFR 164.512\(c\)\(3\)](#) operates as a limitation on disclosure, it is not possible for the new provision to permit disclosures in more circumstances than previously permitted, and therefore does not circumvent the existing provision.

Comment: A commenter recommended that the Department clarify that the proposed Rule of Applicability would not prohibit disclosure and use of such records when they are sought for a defensive purpose by revising the proposed Rule of Construction at [45 CFR 164.512\(c\)\(3\)](#) to more explicitly state that it permits such use or disclosure.

Response: The adopted Rule of Construction at [45 CFR 164.512\(c\)\(3\)](#) applies to disclosures permitted by [45 CFR 164.512\(c\)](#), which are explicitly to a government authority, including a social service or protective services agency, authorized by law to receive reports of abuse, neglect, or domestic violence. The Department is not aware of a disclosure that otherwise meets the requirements specified at [45 CFR 164.512\(c\)\(1\)](#) that would constitute a disclosure for defensive purposes. Rather, disclosures of PHI for defensive purposes, such as a disclosure to defend against a prosecution for criminal prosecution for allegations of providing unlawful health care, are permitted by [45 CFR 164.512\(f\)](#), as well as for health care operations when obtaining legal services. To the extent that a disclosure for a defensive purpose meets the applicable requirements and is permitted, the Department confirms that the final rule language generally would not prohibit a disclosure.

Comment: A few commenters requested clarification of the standard for determining what would constitute a report of abuse, neglect, or domestic violence that is based primarily on the provision of reproductive health care. Commenters also requested clarification about the interaction between the proposed prohibition and the permission at [45 CFR 164.512\(c\)](#).

Response: The Privacy Rule permits but does not require the reporting of abuse, neglect, or domestic violence under certain conditions.[FN393] Under the final rule, the Department is clarifying that this permission does not apply where the sole basis of the report is the provision or facilitation of reproductive health care. With this modification, the Department makes clear that it may be reasonable for a covered entity that is a mandatory reporter to believe that an individual is the victim of abuse, neglect, or domestic violence and to make such report to the government authority authorized by law to receive such reports in circumstances where the provision or facilitation of reproductive health care is but one factor prompting the suspicion. We also note, as discussed above with respect to [45 CFR 164.512\(b\)\(1\)\(i\)](#), this permission allows a covered entity to report known or suspected abuse, neglect, or domestic violence only for the purpose of making a report. The PHI disclosed must be limited to the minimum necessary information for the purpose of making a report.[FN394] These provisions do not permit the covered entity to disclose PHI in response to a request for the use or disclosure of PHI to conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on a person based on suspected abuse, neglect, or domestic violence. Thus, any disclosure of PHI in response to a request from an investigator, whether in follow up to the report made by the covered entity (other than to clarify the PHI provided on the report) or as part of an investigation initiated based on an allegation or report made by a person other than the covered entity, must meet the conditions of disclosures for law enforcement purposes or judicial and administrative proceedings.[FN395]

3. Clarifying the Permission for Disclosures Based on Administrative Processes

Under [45 CFR 164.512\(f\)\(1\)](#), a regulated entity may disclose PHI pursuant to an administrative request, provided that: (1) the information sought is relevant and material to a legitimate law enforcement inquiry; (2) the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and (3) de-identified information could not reasonably be used. Examples of administrative requests include administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law. The examples of administrative requests provided in the regulatory text include only requests that are enforceable in a court of law, and the catchall “or similar process authorized by law” similarly is intended to include only requests that, by law, require a response. This interpretation is consistent with the Privacy Rule’s definition of “required by law,” which enumerates these and other examples of administrative requests that constitute “a mandate contained in law that compels an entity to make a use or disclosure of protected health *33044 information and that is enforceable in a court of law.”

As we explained in the 2023 Privacy Rule NPRM, the Department has become aware that some regulated entities may be interpreting [45 CFR 164.512\(f\)\(1\)](#) in a manner that is inconsistent with the Department’s intent. Therefore, the Department proposed to clarify the types of administrative processes that this provision was intended to address.[FN396]

Specifically, the Department proposed to insert language to clarify that the administrative processes that give rise to a permitted disclosure include only requests that, by law, require a regulated entity to respond. Accordingly, the proposal would specify that PHI may be disclosed pursuant to an administrative request “for which a response is required by law.” The Department does not consider this to be a substantive change because the proposal was consistent with express language of the preamble discussion on this topic in the 2000 Privacy Rule.[FN397] The Department intends that the express inclusion of this language will ensure that regulated entities more fully appreciate the permitted uses and disclosures pursuant to [45 CFR 164.512\(f\)\(1\)\(ii\)\(C\)](#).

The Department received few comments on the proposal to clarify the permission at [45 CFR 164.512\(f\)\(1\)\(ii\)\(C\)](#). Comments were mixed, with some support, some opposition, and some requesting additional modifications or additional examples or guidance.

While the Department received few comments on this clarification, the Department is aware of reports that covered entities are misinterpreting the intention of the requirements of [45 CFR 164.512\(f\)\(1\)\(ii\)\(C\)](#) that disclosures of PHI to law enforcement be

necessary and limited in scope. For example, a congressional inquiry recently highlighted concerns about disclosures of PHI to law enforcement from retail pharmacy chains. The inquiry found that some pharmacy staff are providing PHI directly to law enforcement without advice from their legal departments in part because their staff “face extreme pressure to immediately respond to law enforcement demands.” [FN398] Based on this inquiry, these disclosures often are made without a warrant or subpoena issued by a court.[FN399]

The Department is adopting the clarification as proposed because regulated entities are misinterpreting the requirements of 45 CFR 164.512(f)(1)(ii)(C) that ensure that disclosures of PHI to law enforcement are necessary and limited in scope. Accordingly, the Department is adding to 45 CFR 164.512(f)(1)(ii)(C) language that specifies that PHI may be disclosed pursuant to an administrative request “for which a response is required by law.” Thus, the regulatory text now clearly states that the administrative processes for which a disclosure is permitted are limited to only requests that, by law, require a regulated entity to respond, consistent with preamble discussion on this topic in the 2000 Privacy Rule.[FN400]

Comment: A few commenters supported the Department's proposed clarification of 45 CFR 164.512(f)(1)(ii)(C). A commenter recommended that the Department revise the language to refer to an administrative subpoena or summons, a civil or other “expressly” authorized demand, or other similar process. The commenter recommended that, at a minimum, the Department prohibit disclosures in response to oral requests, require all informal administrative requests be in writing, and require qualifying administrative requests to obtain express supervisory approval.

A commenter asserted, without providing examples, that there are many disclosures currently made under Federal agencies' interpretations of the Privacy Act of 1974 [FN401] that would not be permitted under the NPRM proposal.

Response: The Department appreciates the comments on this clarification. The Department understands the commenter's request to add language identifying specific processes but declines to make the suggested modification at this time. The Department is concerned that references to specific items or actions could be understood to not apply to similarly situated administrative requests understood by different names. In guidance for law enforcement, the Department has provided its interpretation that administrative requests must be accompanied by a written statement.[FN402]

In addition, the Department does not control whether a verbal or other non-written request is sufficient to meet the standards of various jurisdictions for an administrative process that would require a responding covered entity to be legally required to respond. The Department understands that valid, justiciable reasons for responding to a verbal or other non-written request may exist, such as an emergent situation that requires an immediate response to avoid an adverse outcome. The Department believes the additional text sufficiently clarifies the misunderstandings of some regulated entities about what constitutes administrative process for the purposes of this permission.

4. Request for Information on Current Processes for Receiving and Addressing Requests Pursuant to 164.512(d) Through (g)(1)

The Department requested information and comments on certain considerations to help inform development of the final rule.[FN403] In particular, the Department asked how regulated entities currently receive and address requests for PHI when requested pursuant to the Privacy Rule permissions at 45 CFR 164.512(d), (e), (f), or (g)(1), and what effect expanding the scope of the proposed prohibition to include any health care would have on the proposed attestation requirement and the ability of regulated entities to implement it. Comments submitted in response to the question about the effects of expanding the scope of the proposed prohibition have been included in prior discussions of the specific policy issues elsewhere, as applicable.

Comment: Several commenters responded to this request for information concerning current processes for receiving certain requests pursuant to 45 CFR 164.512 by providing specific information about how they receive such requests. Some requests for PHI are received in hard copy, either by mail or hand delivery, while others are received via email. Still *33045 others are received through the regulated entities online portal or facsimile. In emergency circumstances, such requests may be received verbally. Commenters generally receive assurances through hard copy, email, their patient portal, and fax. A few commenters

seek assurances for every subsequent related request, while another commenter stated that it does not require or obtain assurances for every subsequent related request if the subsequent request is related to the initial request for which the initial assurance was received.

A commenter asserted that the privacy interests at stake outweigh potential administrative burdens and provided examples of state laws that are more privacy protective than the Privacy Rule. The commenter explained that the privacy landscape is constantly evolving, as do the HIPAA Rules, and as such, regulated entities must adapt in response.

Response: The Department appreciates the information provided by commenters explaining the processes by which regulated entities currently receive requests for the use or disclosure of PHI for certain purposes and the workflows of regulated entities to ensure that such requests comply with the conditions of the applicable Privacy Rule permissions. We reviewed and considered this information when evaluating the burden of the proposed modifications to the Privacy Rule during the development of this final rule.

E. Section 164.520—Notice of Privacy Practices for Protected Health Information

1. Current Provision

The Privacy Rule generally requires that a covered entity provide individuals with an NPP to ensure that they understand how a covered entity may use and disclose their PHI, as well as their rights and the covered entity's legal duties with respect to PHI. [FN404] Section 164.520(b)(1)(ii) of the Privacy Rule describes the required contents of the NPP, including descriptions of the types of permitted uses and disclosures of their PHI. More specifically, the NPP must describe the ways in which the covered entity may use and disclose PHI for TPO, as well as each of the other purposes for which the covered entity is permitted or required to use or disclose PHI without the individual's written authorization. Additionally, the NPP must state the covered entity's duties to protect privacy, provide a copy of the NPP, and abide by the terms of the current notice. The NPP must also describe individuals' rights, including the right to complain to HHS and to the covered entity if they believe their privacy rights have been violated, as well as other statements if the covered entity uses PHI for certain activities, such as fundraising. The Privacy Rule does not, however, currently require a covered entity to provide information about specific prohibited uses and disclosures of PHI.

2. CARES Act

Section 3221(i) of the CARES Act directs the Secretary to modify the NPP provisions at [45 CFR 164.520](#) to include new requirements for covered entities that create or maintain PHI that is also a record of SUD treatment provided by a Part 2 program (i.e., covered entities that are Part 2 programs and covered entities that receive Part 2 records from a Part 2 program). The CARES Act amended [42 U.S.C. 290dd-2](#) to require the Department to revise Part 2 to more closely align with the Privacy Rule.

3. Proposals in 2022 Part 2 NPRM and 2023 Privacy Rule NPRM

The Department proposed in December 2022 to modify both the Patient Notice requirements at [42 CFR 2.22](#) and the NPP requirements at [45 CFR 164.520](#) to provide consistent notice requirements for all Part 2 records. Revisions to the Patient Notice requirements were addressed and finalized in the 2024 Part 2 Rule, while modifications to the NPP provisions proposed in the 2022 Part 2 NPRM were deferred to a future rulemaking. The Department also separately proposed to modify the NPP provisions to support reproductive health care privacy as part of the 2023 Privacy Rule NPRM.

As part of the 2022 Part 2 NPRM, the Department proposed several changes to the NPP provisions. We proposed in a new paragraph (2) to [45 CFR 164.520\(a\)](#) that individuals with Part 2 records that are created or maintained by covered entities would have a right to adequate notice of uses and disclosures, their rights, and the responsibilities of covered entities with respect to such records. The Department also proposed to remove [45 CFR 164.520\(a\)\(3\)](#), the exception for providing inmates a copy of the NPP, which would require covered entities that serve correctional facilities to provide inmates with a copy of the NPP.

Additionally, the Department proposed revising [45 CFR 164.520\(b\)\(1\)](#) to specifically clarify that covered entities that maintain or receive Part 2 records would need to provide an NPP that is written in plain language and contains the notice's required elements. We also proposed to modify [45 CFR 164.520\(b\)\(1\)\(i\)](#) to replace “medical” with “health” information.

The Department also proposed in the 2022 Part 2 NPRM to incorporate changes proposed to the NPP requirements in the 2021 Privacy Rule NPRM,[FN405] such as adding a requirement to include the email address for a designated person who would be available to answer questions about the covered entity's privacy practices; adding a permission for a covered entity to provide information in its NPP concerning the individual access right to direct copies of PHI to third parties when the PHI is not in an EHR and the ability to request the transmission using an authorization; and removing the requirement for a covered entity to obtain a written acknowledgment of receipt of the NPP. The Department is finalizing certain changes proposed in the 2022 Part 2 NPRM and the 2023 Privacy Rule NPRM that directly support the two final rules.

In both the 2022 Part 2 NPRM and 2023 Privacy Rule NPRM, the Department proposed to modify [45 CFR 164.520\(b\)\(1\)\(ii\)](#), which requires covered entities to describe for individuals the purposes for which a covered entity is permitted to use and disclose PHI. Consistent with the CARES Act, we proposed in the 2022 Part 2 NPRM to modify paragraph (C) to clarify that where uses and disclosures are prohibited or materially limited by other applicable law, “other applicable law” would include Part 2, while the Department proposed to clarify at paragraph (D) that the requirement for a covered entity to include in the NPP sufficient detail to place an individual on notice of the uses and disclosures that are permitted or required by the Privacy Rule and other applicable laws, including Part 2.

The Department further proposed to require in [45 CFR 164.520\(b\)\(1\)\(iii\)](#), which requires covered entities to include descriptions of certain activities in which the covered entity intends to engage, in a new paragraph (D) the inclusion of a statement that Part 2 records created or maintained by the covered entity will not be used in certain proceedings against the individual without the individual's written consent or a court order consistent with 42 CFR part 2. Additionally, we proposed to require in a new paragraph (E) that covered entities that intend to use Part 2 records for fundraising include a statement that ***33046** such records may be used or disclosed for fundraising purposes only if the individual grants written consent as provided in [42 CFR 2.31](#).

In [45 CFR 164.520\(b\)\(1\)\(v\)\(C\)](#), which addresses a covered entity's right to change the terms of its notice, we also proposed to simplify and modify the regulatory text to clarify that this right is limited to circumstances where such changes are not material or contrary to law. The Department also proposed to add a new paragraph (4) to [45 CFR 164.520\(d\)](#) to prohibit construing permissions for covered entities participating in organized health care arrangements [FN406] (OHCAs) to disclose PHI between participants as negating obligations relating to Part 2 records.

The 2023 Privacy Rule NPRM also proposed modifications to the NPP requirements.[FN407] Specifically, the Department proposed to modify [45 CFR 164.520\(b\)\(1\)\(ii\)](#) by adding a new paragraph (F) to require a covered entity to describe and provide an example of the types of uses or disclosures prohibited by [45 CFR 164.502\(a\)\(5\)\(iii\)](#), and to do so in sufficient detail for an individual to understand the prohibition. We also proposed adding a new paragraph (G) to [45 CFR 164.502\(b\)\(1\)\(ii\)](#) to describe each type of use and disclosure for which an attestation is required under [45 CFR 164.509](#), with an example. Additionally, the Department requested comment on whether it would benefit individuals for the Department to require that covered entities include a statement in the NPP that would explain that the recipient of the PHI would not be bound by the proposed prohibition because the Privacy Rule would no longer apply after PHI is disclosed for a permitted purpose to an entity other than a regulated entity (e.g., disclosed to a non-covered health care provider for treatment purposes).

4. Overview of Public Comments

We received many comments on the proposed NPP changes in both the 2022 Part 2 NPRM and the 2023 Privacy Rule NPRM. Some of the comments on the 2022 Part 2 NPRM addressed both the NPP and the Patient Notice. Comments concerning the Patient Notice are discussed in the 2024 Part 2 Rule.[FN408] Commenters on the NPP proposals in the 2022 Part 2 NPRM urged the Department to coordinate revisions to the NPP provisions across its proposed and final rules. Commenters also requested guidance about their ability to use a single form to satisfy both the NPP and Patient Notice requirements. Commenters

generally expressed support for the Department's proposals to modify [45 CFR 164.520\(a\)](#) and [164.520\(b\)\(1\)](#) to apply the NPP requirements to certain entities, in coordination with changes required by the CARES Act and consistent with Part 2.

Commenters to the 2022 Part 2 NPRM generally did not express opposition to the Department's proposed changes to paragraph (b)(iii) of [45 CFR 164.520](#), although some did request additional guidance. We received no comments on our proposed modifications to add a new paragraph concerning OHCA's to [45 CFR 164.520\(d\)](#).

Most commenters expressed support for the Department's 2023 Privacy Rule NPRM proposals to revise the NPP requirements. Many also recommended additional modifications to the NPP requirements or clarifications to the requirements. Most also recommended that the Department add a requirement that NPPs include a statement that would explain that the recipient of PHI would not be bound by the proposed prohibition because the Privacy Rule would no longer apply after PHI is disclosed for a permitted purpose to an entity other than a regulated entity (e.g., disclosed to a non-covered health care provider for treatment purposes).

5. Final Rule

The Department published the 2024 Part 2 Rule on February 16, 2024. It included modifications to the Patient Notice in [42 CFR 2.22](#) and reserved modifications to the HIPAA NPP for a forthcoming HIPAA rule. We address the modifications proposed in the 2022 Part 2 NPRM here, in concert with the modifications proposed in the 2023 Privacy Rule NPRM.

As required by the CARES Act and in alignment with the Privacy Rule, we are modifying the NPP provisions in multiple ways. First, we are requiring in [45 CFR 164.520\(a\)\(2\)](#) that covered entities that create or maintain Part 2 records provide notice to individuals of the ways in which those covered entities may use and disclose such records, and of the individual's rights and the covered entities' responsibilities with respect to such records. Second, we are revising [45 CFR 164.520\(b\)\(1\)](#) to clarify that a covered entity that receives or maintains records subject to Part 2 must provide an NPP that is written in plain language and that contains the elements required. For clarity, we have reordered wording within this paragraph to refer to “receiving or maintaining” records, rather than “maintaining or receiving” records as initially proposed.

Third, the Department is modifying [45 CFR 164.520\(b\)\(1\)\(ii\)](#) to revise paragraphs (C) and (D), and to add paragraphs (F), (G), and (H) to clarify certain statements and add new statements that must be included in an NPP. Consistent with the CARES Act, we are modifying paragraph (C) to clarify that where NPP's descriptions of uses or disclosures that are permitted for TPO or without an authorization must reflect “other applicable law” that is more stringent than the Privacy Rule, other applicable law includes Part 2. Likewise, we are modifying paragraph (D) to clarify that Part 2 is specifically included in the “other applicable law” referenced in the requirement to describe uses and disclosures that are permitted for TPO or without an authorization sufficiently to place an individual on notice of the uses and disclosures that are permitted or required by the Privacy Rule and other applicable law.

New paragraphs (F) and (G) provide individuals with additional information about how their PHI may or may not be disclosed for purposes addressed in this rule, furthering trust in the relationship between regulated entities and individuals by ensuring that individuals are aware that certain uses and disclosures of PHI are prohibited. Specifically, paragraph (F) requires that the NPP contain a description, including at least one example, of the types of uses and disclosures prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#) in sufficient detail for an individual to understand the prohibition, while paragraph (G) requires that the NPP contain a description, including at least one example, of the types of uses and disclosures for which an attestation is required under new [45 CFR 164.509](#).

Additionally, based on feedback from commenters, we are requiring in a new paragraph (H) that covered entities include a statement explaining to individuals that PHI disclosed pursuant to the Privacy Rule may be subject to redisclosure and no longer protected by the Privacy Rule. This will help individuals to make informed decisions about to whom they provide access to or authorize the disclosure of their PHI.

Under new paragraph (D) of 45 CFR 164.520(b)(1)(iii), the Department is requiring that covered entities provide notice to individuals that a Part 2 record, or testimony relaying the content of such record, may not be used or disclosed in a civil, criminal, administrative, or legislative proceeding against the individual absent written *33047 consent from the individual or a court order, consistent with the requirements of 42 CFR part 2.

The Department is also finalizing a requirement at 45 CFR 164.520(b)(1)(iii)(E) that a covered entity must provide individuals with a clear and conspicuous opportunity to elect not to receive any fundraising communications before using Part 2 records for fundraising purposes for the benefit of the covered entity.

Lastly, we are finalizing our proposal to add a new paragraph (4) in 45 CFR 164.520(d) regarding joint notice by separate covered entities. This modification clarifies that Part 2 requirements continue to apply to Part 2 records maintained by covered entities that are part of OHCAs.

We are not finalizing in this rule the proposal to remove the exception to the NPP requirements for inmates of correctional facilities in this rule because it would be better addressed within the context of care coordination.

6. Responses to Public Comments

Comment: Commenters on both the 2022 Part 2 NPRM and the 2023 Privacy Rule NPRM urged the Department to coordinate any changes made to the NPP provisions based on proposals made in the separate rulemakings. According to the commenters, coordinating the changes to the NPP requirements would help to ensure consistency, reduce the administrative burden on covered entities, and ensure individual understanding of the permitted uses and disclosures of their PHI, including PHI that is also a Part 2 record. A few commenters on the 2022 Part 2 NPRM explained the different concerns that updates to the NPP pose to covered entities of differing sizes, based on resource constraints directly related to their size. Several commenters on the 2023 Privacy Rule NPRM requested that the Department provide sample language and examples or provide an updated model NPP.

Response: As part of this rulemaking, the Department is finalizing modifications to certain NPP requirements that were proposed in the 2022 Part 2 NPRM and the 2023 Privacy Rule NPRM. Thus, these changes serve to implement certain requirements of the CARES Act and to support reproductive health care privacy. The Department appreciates the recommendations and will consider them for future guidance.

Comment: A few commenters on the 2022 Part 2 NPRM requested that the Department clarify whether they would be permitted to use a single document or form when providing notice statements to individuals to ensure compliance by regulated entities and understanding of the notices by individuals. A few commenters agreed that a single NPP would reduce the administrative burden on regulated entities or be the most effective way to convey privacy information to individuals and asked for confirmation that this was permitted. A commenter requested that the Department update the Patient Notice in a manner such that the NPP header may be used in the combined notice if they are permitted to use a combined NPP/Patient Notice.

Response: As we have provided previously in guidance on the Privacy Rule and Part 2, notices issued by covered entities for different purposes may be separate or combined, as long as all of the required elements for both are included.[FN409] Thus, it is acceptable under both the Privacy Rule and Part 2 to meet the notice requirements of the Privacy Rule, Part 2, and state law by either providing separate notices or combining the required notices into a single notice, as long as all of the required elements are included.

Comment: A few commenters on the 2022 Part 2 NPRM and most of the commenters on the 2023 Privacy Rule NPRM suggested the proposed approach to modifying both the Patient Notice and NPP would bolster transparency and the public's understanding of how their health information is used or disclosed and collected. Many commenters on the 2023 Privacy Rule NPRM provided recommendations for ways in which the Department could improve the NPP, including requiring that the NPP be in plain language.

Response: The Department appreciates the comments on its proposal to modify the NPP to align with changes made in the Patient Notice and in support of reproductive health care privacy. The modifications will bolster transparency and public understanding of how information is used, disclosed, and protected. Covered entities have long been required under [45 CFR 164.520\(b\)\(1\)](#) to provide an NPP that is written in plain language. Discussion of this requirement can be found in the preamble to the 2000 Privacy Rule.[FN410] The Department's model NPP forms, available in both English and Spanish, provide one example of how the plain language requirement may be met.[FN411]As discussed above, we are modifying [45 CFR 164.520](#) to clarify that this requirement applies to covered entities that use and disclose Part 2 records. Additional resources on writing in plain language can be found at <https://plainlanguage.gov>. Additionally, covered entities are required to comply with all Federal nondiscrimination laws, including laws that address language access requirements. Information about such requirements is available at www.hhs.gov/hipaa.

Comment: Commenters expressed concerns about the interplay of the Part 2 Patient Notice requirements with the NPP, the burden on covered entities to modify the NPP, and including the attestation requirement in the NPP.

Response: We have sought to align the requirements for the Patient Notice as closely as possible with the NPP requirements and to modify the NPP requirements to allow for a combined Patient Notice and NPP. The changes the Department is making to the NPP empower the individual and improve health outcomes by improving the likelihood that health care providers will make accurate diagnoses and informed treatment recommendations to individuals. These changes to the NPP provide the individual with clear information and reassurance about their privacy rights and their ability to discuss their reproductive health and related health care because they inform an individual that their PHI may not be used or disclosed for certain purposes prohibited by new [45 CFR 164.502\(a\)\(5\)\(iii\)](#). As such, the qualitative benefits of providing individuals with information about how their PHI may be used and disclosed under the Privacy Rule outweigh the quantitative burdens for covered entities to revise their NPPs. Accordingly, we are finalizing the modifications proposed to the NPP as part of the 2023 Privacy Rule NPRM.

Comment: A majority of the commenters on the 2023 Privacy Rule NPRM who expressed support for revising the NPP also recommended that the Department require that the NPP include an explanation that the prohibition or Privacy Rule generally would no longer apply to PHI that has been disclosed for a permitted purpose to a person that is not a regulated entity. A few commenters opposed the addition as unnecessary or expressed concern about the potential length of the NPP. A ***33048** few of the commenters opposed adding such a statement because they believed it could deter individuals from seeking reproductive health care, increase individuals' mistrust of health care providers, or not add to individuals' understanding of their rights and protections under the Privacy Rule.

Response: In response to comments and in support of transparency for individuals, the Department is finalizing a new requirement to include in the NPP a statement adequate to put the individual on notice of the potential for information disclosed pursuant to the Privacy Rule to be subject to redisclosure by the recipient and no longer protected by the Privacy Rule. This change will provide additional clarity to individuals directly and assist covered entities in explaining the limitations of the Privacy Rule to individuals. We believe that any concerns about the negative effects of these modifications on length are outweighed by their benefits to the individual.

Comment: Several commenters to the 2023 Privacy Rule NPRM requested the Department provide additional time for compliance with the new NPP requirements and exercise enforcement discretion for a period of time after the compliance date.

Response: As noted above, we are finalizing certain modifications to the NPP provisions that were proposed in the 2022 Part 2 NPRM rule and other modifications to the same provisions that were proposed in the 2023 Privacy Rule NPRM. To ease the burden on covered entities and in compliance with [45 CFR 160.104](#), the Department is finalizing a compliance date of February 16, 2026, for the NPP provisions. The rationale for this compliance date is discussed in greater detail in the discussion of Effective and Compliance Dates.

F. Section 164.535—Severability

In the NPRM, the Department included a discussion of severability that explained how we believed the proposed rule should be interpreted if any provision was held to be invalid or facially unenforceable. We are finalizing a new [45 CFR 164.535](#) to codify this interpretation. The Department intends that, if a specific regulatory provision in this rule is found to be invalid or unenforceable, the remaining provisions of the rule will remain in effect because they would still function sensibly.

For example, the changes this final rule makes to the NPP requirements in [45 CFR 164.520](#) (including the changes finalizing proposals from the 2022 Part 2 NPRM) shall remain in full force and effect to the extent that they are not directly related to a provision in this rulemaking that is held to be invalid or unenforceable such that notice of that provision is no longer necessary. Conversely, if the NPP requirements are held to be invalid or unenforceable, the other modifications shall remain in full force and effect to the extent that they are not directly related to the NPP requirements.

As another example, we also intend that the revision in [45 CFR 160.103](#) to the definition of “person” shall remain in full force and effect if any other provision is held to be invalid or unenforceable because the new modified definition is not solely related to supporting reproductive health care privacy and is consistent with the Department's longstanding interpretation of the term and with regulated entities' current understanding and practices.

Similarly, we are finalizing technical corrections to the heading at [45 CFR 164.512\(c\)](#) and a clarifying revision at [45 CFR 164.512\(f\)](#) regarding the permission for disclosures based on administrative processes. Those changes are intended to remain in full force and effect even if other parts of this final rule are held to be invalid or unenforceable.

As another example, we also intend, if the addition in [45 CFR 160.103](#) of the definition of “public health,” as used in the terms “public health surveillance,” “public health investigation,” and “public health intervention” is held to be invalid and unenforceable, the other modifications to the rules shall remain in full force and effect to the extent that they are not directly related to the definition of public health.

We further intend that if the rule is held to be invalid and unenforceable with respect to its application to some types of health care, it should be upheld with respect to other types (e.g., pregnancy or abortion-related care).

We also intend that any provisions of the Privacy Rule that are unchanged by this final rule shall remain in full force and effect if any provision of this final rule is held to be invalid or unenforceable.

These examples are illustrative and not exhaustive.

We received no comments on the language addressing severability in the 2023 Privacy Rule NPRM.

G. Comments on Other Provisions of the HIPAA Rules

Comment: A few commenters expressed concerns that the Department may grant exceptions to preemption and recommended that the Department clarify the standards for which exceptions to preemption would be made and consider strengthening these standards wherever possible or remove the potential for exceptions entirely.

One commenter expressed concern that the proposed rule could dissuade regulated entities from providing de-identified data for research, while another commenter recommended that the Department prohibit the sharing of de-identified reproductive health care data except in limited circumstances to prevent the re-identification of reproductive health data by third parties, such as law enforcement or data brokers

Response: The process for requesting exceptions to preemption and the standards for granting such requests are at [45 CFR 160.201 et seq.](#) We did not propose any modifications to these provisions as part of the 2023 Privacy Rule NPRM, and as such, do not finalize modifications in this final rule.

The Department does not believe that this final rule will dissuade regulated entities from providing de-identified data for research or other purposes. Under the Privacy Rule, health information that meets the standard and implementation specifications for de-identification under [45 CFR 164.514](#) is considered not to be IIHI.[FN412] HIPAA confers on the Department the authority to set standards for the privacy of IIHI, including for de-identification. We did not propose to modify the de-identification standard as part of the 2023 Privacy Rule NPRM, and as such, do not finalize modifications in this final rule.

Comment: A commenter posited that the proposed rule's preemption of contrary state laws was not sufficiently clear and recommended that the Department reinforce the preemption provision in the final rule.

Response: The Department did not propose changes to the preemption provisions of the HIPAA Rules, which are based in statute, [FN413] and believes that the provisions, in combination with our discussion of preemption in the preamble, are sufficient.

VI. Regulatory Impact Analysis

A. Executive Order 12866 and Related Executive Orders on Regulatory Review

The Department of Health and Human Services (HHS or “Department”) has examined the effects of this final rule under [Executive Order \(E.O.\) 12866](#), Regulatory Planning and Review,[FN414] as ~~*33049~~ amended by [E.O. 14094](#),[FN415] [E.O. 13563](#), Improving Regulation and Regulatory Review,[FN416] the Regulatory Flexibility Act [FN417] (RFA), and the Unfunded Mandates Reform Act of 1995 [FN418] (UMRA). E.O.s 12866 and 13563 direct the Department to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive effects; and equity). This final rule is significant under section 3(f)(1) of [E.O. 12866](#), as amended.

The RFA requires us to analyze regulatory options that would minimize any significant effect of a rule on small entities. As discussed in greater detail below, this analysis concludes, and the Secretary certifies, that the rule will not result in a significant economic effect on a substantial number of small entities.

The UMRA (section 202(a)) generally requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” [FN419] The current threshold after adjustment for inflation is \$177 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly Federal mandate costs resulting from imposing enforceable duties on state, local, or Tribal governments or the private sector; or increasing the stringency of conditions in, or decreasing the funding of, state, local, or Tribal governments under entitlement programs. This final rule imposes mandates that would result in the expenditure by state, local, and Tribal governments, in the aggregate, or by the private sector, of more than \$177 million in any one year. The impact analysis in this final rule addresses such effects both qualitatively and quantitatively. In general, each regulated entity, including government entities that meet the definition of covered entity (e.g., state Medicaid agencies), is required to adopt new policies and procedures for responding to requests for the use or disclosure of protected health information (PHI) for which an attestation is required and to train its workforce members on the new requirements. Additionally, although the Department has not quantified the costs, state, local, and Tribal law enforcement agencies must analyze requests that they initiate for the use or disclosure of PHI and provide regulated entities with an attestation that the request is not for a prohibited purpose in instances where the request is made for health oversight activities, judicial and administrative proceedings, law enforcement purposes, or about decedents to coroners and medical examiners, and is for PHI potentially related to reproductive health care. One-time costs for all regulated entities to change their policies will increase costs above the UMRA threshold in one year. The Department initially estimated that ongoing expenses for the new attestation condition would not increase significantly, but we sought additional data to inform our estimates. Although Medicaid makes Federal matching funds available for states for certain administrative costs, these are limited to costs specific to operating the Medicaid program. There are no Federal funds directed at Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliance activities.

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996,[FN420] the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs has determined that this final rule meets the criteria set forth in 5 U.S.C. 804(2) because it is projected to have an annualized effect on the economy of more than \$100,000,000. Because of the large number of covered entities that are subject to this final rule and the large number of individuals with health plan coverage, any rule modifying the HIPAA Privacy Rule that requires updating policies and procedures and the Notice of Privacy Practices (NPP) and distributing the NPP to a percentage of individuals is likely to meet the threshold in 5 U.S.C. 804(2).

The Justification for this Rulemaking and Summary of Final Rule Provisions section at the beginning of this preamble contain a summary of this rule and describe the reasons it is needed. The Department presents a detailed analysis below.

1. Summary of Costs and Benefits

The Department identified six general categories of quantifiable costs arising from these proposals: (1) responding to requests for the use or disclosure of PHI for which an attestation is required; (2) revising business associate agreements; (3) updating the NPP and posting it online; (4) developing new or modified policies and procedures; (5) revising training programs for workforce members; and (6) requesting an exception from HIPAA's general preemption authority. The first five categories apply primarily to covered entities, while the sixth category applies to states and other interested persons.

The Department estimates that the first-year costs attributable to this final rule total approximately \$595.0 million. These costs are associated with covered entities responding to requests for the use or disclosure of PHI that are conditioned upon an attestation; revising business associate agreements; revising policies and procedures; updating, posting, and mailing the NPP; and revising training programs for workforce members, and with states or other persons requesting exceptions from preemption. These costs also include increased estimates for wages, postage, and the number of NPPs distributed by health plans as compared to the baseline of existing annual cost and burden estimates for these activities in the approved HIPAA information collection. For years two through five, estimated annual costs of approximately \$20.9 million are attributable to ongoing costs related to the attestation requirement. Table 1 reports the present value and annualized estimates of the costs of this final rule covering a 5-year time horizon. Using a 7% discount rate, the Department estimates this final rule will result in annualized costs of \$151.8 million; and using a 3% discount rate, these annualized costs are \$142.6 million.

Table 1—Accounting Table, Costs of the Rule

[\$ Millions]				
Costs	Primary	Year	Discount	Period
	estimate			
		dollars		
			rate	
			(%)	
				covered
Present Value	\$678.6	2022	Undiscounted	2024-2028
Present Value	622.3	2022		7 2024-2028
Present Value	653.1	2022		3 2024-2028

Annualized	151.8	2022	7 2024-2028
Annualized	142.6	2022	3 2024-2028

***33050** The changes to the Privacy Rule will likely result in important benefits and some costs that the Department is unable to fully quantify at this time. As explained further below, unquantified benefits include improved trust and confidence between individuals and health care providers; enhanced privacy and improved access to reproductive health care and information, which may prevent increases in maternal mortality and morbidity; increased accuracy and completeness in patient medical records, which may prevent poor health outcomes; enhanced support for survivors of rape, incest, and sex trafficking; and maintenance of family economic stability by allowing families to determine the timing and spacing of whether or when to be pregnant. Additionally, allowing regulated entities to accept an attestation for requests for the use or disclosure of PHI potentially related to reproductive health care, and to presume that reproductive health care provided by another person was lawful under the circumstances it was provided, will reduce potential liability for regulated entities by providing some assurance with respect to whether the requested disclosure is prohibited.

Table 2—Potential Non-Quantified Benefits for Covered Entities and Individuals

Benefits
Improve access to complete information about lawful reproductive health care options, including for individuals who are pregnant or considering a pregnancy (i.e., improve health literacy), by reducing concerns about disclosure of PHI.
Maintain or reduce levels of maternal mortality and morbidity by ensuring that individuals and their clinicians can freely communicate and have access to complete information needed for quality lawful health care, including coordination of care.
Decrease barriers to accessing prenatal health care by maintaining privacy for individuals who seek a complete range of lawful reproductive health care options.
Enhance mental health and emotional well-being of pregnant individuals by reducing fear of potential disclosures of their PHI to investigate or impose liability on a person for the mere act of seeking, obtaining, providing, or facilitating lawful health care.
Improve or maintain trust between individuals and health care providers by reducing the potential for health care providers to report PHI in a manner that could harm the individuals' interests.
Prevent or reduce re-victimization of pregnant individuals who have survived rape or incest by protecting their PHI from undue scrutiny.
Improve or maintain families' economic well-being by not exposing individuals or their family members to costly investigations or activities to impose liability for seeking, obtaining or facilitating lawful reproductive health care.
Maintain the economic well-being of regulated entities by not exposing regulated entities or workforce members to costly investigations or activities to impose liability on them for engaging in lawful activities.
Ensure individuals' ability to obtain full and complete information and make lawful decisions concerning fertility- or infertility-related health care that may include selection or disposal of embryos without risk of PHI disclosure for criminal, civil, or administrative investigations or activities to impose liability for engaging in lawful activities.
The Department also recognizes that there may be some costs that are not readily quantifiable, notably, the potential burden on persons requesting PHI to investigate or impose liability on persons for seeking, obtaining, providing, or facilitating reproductive health care that is not lawful under the circumstances in which such health care is provided. As discussed elsewhere in this final rule, we acknowledge that, in certain limited circumstances, the final rule may, prevent persons from obtaining an individual's PHI, such as where the request is directed to the health care provider that provided the reproductive health care and that

health care provider reasonably determines that such health care was provided lawfully. However, the existing permission for disclosures for law enforcement does not create a mandate for disclosure to law enforcement agencies. Rather, it establishes the conditions under which a regulated entity may disclose PHI if it so chooses. Accordingly, consistent with how the Privacy Rule has operated since its inception, persons whose requests for PHI are declined by regulated entities may incur additional costs if they choose to pursue their investigations through other methods and obtain evidence from non-covered entities. We have not previously quantified the costs to such persons for obtaining an individual's PHI, such as where a law enforcement official is required to prepare a formal administrative request or obtain a qualified protective order and we do not do so here. We do not view the attestation requirement as changing this calculus and have designed the attestation to impose a minimal burden on requests for PHI related to lawful conduct by health care providers by offering a model attestation form. Despite the minimal formality of providing a signed attestation, some state law enforcement agencies may experience the requirement as a burden, and we acknowledge that potential as a non-quantifiable cost.

2. Baseline Conditions

The Privacy Rule, in conjunction with the Security and Breach Notification Rules, protects the privacy and security of individuals' PHI, that is, individually identifiable health information (IIHI) transmitted by or maintained in electronic media or any other form or ***33051** medium, with certain exceptions. It limits the circumstances under which regulated entities are permitted or required to use or disclose PHI and requires covered entities to have safeguards in place to protect the privacy of PHI. The Privacy Rule also establishes certain rights for individuals with respect to their PHI and sets limits and conditions on the uses and disclosures that may be made of such information without an individual's authorization.

As explained in the preamble, the Department has the authority under HIPAA to modify the Privacy Rule to prohibit the use or disclosure of PHI for activities to conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it was provided, as well as to identify any person for the purpose of initiating such activities. The Privacy Rule has been modified several times since it was first issued in 2000 to address statutory requirements, changed circumstances, and concerns and issues raised by stakeholders regarding the effects of the Privacy Rule on regulated entities, individuals, and others. Recently, as the preamble discusses, changed circumstances resulting from new inconsistencies in the regulation of reproductive health care nationwide and the negative effects on individuals' expectations for privacy and their relationships with their health care providers, as well as the additional burdens imposed on regulated entities, require the modifications made by this final rule.

For purposes of this Regulatory Impact Analysis (RIA), this final rule adopts the list of covered entities and cost assumptions identified in the Department's 2023 Information Collection Request (ICR).[FN421] The Department also relies on certain estimates and assumptions from the 1999 Privacy Rule NPRM [FN422] that remain relevant, and the 2013 Omnibus Rule, [FN423] as referenced in the analysis that follows.

The Department quantitatively analyzes and monetizes the effect that this final rule may have on regulated entities' actions to: revise business associate agreements between covered entities and their business associates, including release-of-information contractors; create new forms; respond to certain types of requests for PHI; update their NPPs; adopt policies and procedures to implement the requirements of this final rule; and train their employees on the updated policies and procedures. The Department analyzes the remaining benefits and burdens qualitatively because of the uncertainty inherent in predicting other concrete actions that such a diverse scope of regulated entities might take in response to this rule.

Analytic Assumptions

The Department bases its assumptions for calculating estimated costs and benefits on several publicly available datasets, including data from the U.S. Census, the U.S. Department of Labor, Bureau of Labor Statistics, Centers for Medicare & Medicaid Services, and the Agency for Healthcare Research and Quality. For the purposes of this analysis, the Department assumes that benefits plus indirect costs equal approximately 100 percent of pre-tax wages and adjusts the hourly wage rates by multiplying

by two, for a fully loaded hourly wage rate. The Department adopts this as the estimate of the hourly value of time for changes in time use for on-the-job activities.

Implementing the regulatory changes likely will require covered entities to engage workforce members or consultants for certain activities. The Department assumes that a lawyer will draft or review the new attestation form, revisions to business associate agreements, revisions to the NPP, and required changes to HIPAA policies and procedures. The Department expects that a training specialist will revise the necessary HIPAA training and that a web designer will post the updated NPP. The Department further anticipates that a workforce member at the pay level of medical records specialist will confirm receipt of required attestations. To the extent that these assumptions affect the Department's estimate of costs, the Department solicited comment on its assumptions, particularly assumptions in which the Department identifies the level of workforce member (e.g., clerical staff, professional) that will be engaged in activities and the amount of time that particular types of workforce members spend conducting activities related to this RIA as further described below. Table 3 also lists pay rates for occupations referenced in the explanation of estimated information collection burdens in Section F of this RIA and related tables.

The Department received several comments about the occupations engaged in certain activities and the time burden associated with them. We reviewed these submissions and used the provided information to revise the estimate for the cost of processing requests for the use or disclosure of PHI that require an attestation. For more details, please see the sections discussing the costs of the rule below.

The Department received no comment on the hourly value of time; therefore, we retain all relevant assumptions laid out in the 2023 Privacy Rule NPRM, as described above (see Table 3 for a list of occupations and corresponding wages).[FN424]

Table 3—Occupational Pay Rates

Occupation code and title	Mean hourly wage	Fully loaded hourly wage
00-0000 All Occupations	\$29.76	\$59.52
43-3021 Billing and Posting Clerks	21.54	43.08
29-0000 Healthcare Practitioners and Technical Occupations	46.52	93.04
29-9021 Health Information Technologists and Medical Registrars	31.38	62.76
29-9099 Healthcare Practitioners and Technical Workers, All Other	32.78	65.56
15-1212 Information Security Analysts	57.63	115.26
23-1011 Lawyers	78.74	157.48
13-1111 Management Analysts	50.32	100.64
11-9111 Medical and Health Services Manager	61.53	123.06
29-2072 Medical Records Specialist	24.56	49.12
43-0000 Office and Administrative Support Occupations	21.90	43.80

11-2030 Public Relations and Fundraising Managers	68.56	137.12
13-1151 Training and Development Specialist	33.59	67.18
43-4171 Receptionists and Information Clerks	16.64	33.28
15-1255 Web and Digital Interface Designers	48.91	97.82

***33052** The Department assumes that most covered entities will be able to incorporate changes to their workforce training into existing HIPAA training programs rather than conduct a separate training because the total time frame for compliance from date of finalization would be 240 days.[FN425]

Covered Entities Affected

The Department received no substantive comments on the number or type of HIPAA covered entities affected by this rule; therefore, we retain the methodology and entity estimates as described in the 2023 Privacy Rule NPRM and the baseline conditions section above.

To the extent that covered entities engage business associates to perform activities under the rule, the Department assumes that any additional costs will be borne by the covered entities through their contractual agreements with business associates. The Department's estimate that each revised business associate agreement will require no more than 1 hour of a lawyer's labor assumes that the hourly burden could be split between the covered entity and the business associate. Thus, the Department calculated estimated costs based on the potential number of business associate agreements that will be revised rather than the number of covered entities or business associates with revised business associate agreements.

The Department requested data on the number of business associates (which may include health care clearinghouses acting in their role as business associates of other covered entities) that would be affected by the rule and the extent to which they may experience costs or other burdens not already accounted for in the estimates of burdens for revising business associate agreements. The Department also requested comment on the number of business associate agreements that would need to be revised, if any. We did not receive any actionable comments on the number of affected business associates, the number of business associate agreements, or any specific costs that business associates might bear. For more details, see the section on business associate agreements below.

The Department requested public comment on these estimates, including estimates for third party administrators and pharmacies where the Department has provided additional explanation. The Department additionally requested detailed comment on any situations, other than those identified here, in which covered entities would be affected by this rulemaking. We did not receive any substantive comments related to these issues.

Table 4—Estimated Number and Type of Covered Entities

Covered entities			
NAICS code	Type of entity	Firms	Establishments
524114	Health and Medical Insurance Carriers	880	5,379
524292	Third Party Administrators	456	783

622	Hospitals	3,293	7,012
44611	Pharmacies	19,540	a 67,753
6211-6213	Office of Drs. & Other Professionals	433,267	505,863
6215	Medical Diagnostic & Imaging	7,863	17,265
6214	Outpatient Care	16,896	39,387
6219	Other Ambulatory Care	6,623	10,059
623	Skilled Nursing & Residential Facilities	38,455	86,653
6216	Home Health Agencies	21,829	30,980
532283	Home Health Equipment Rental	611	3,197
Total		549,713	774,331

*33053 Individuals Affected

The Department believes that the population of individuals potentially affected by the rule is approximately 76 million overall, [FN426] representing nearly one-fourth of the U.S. population, including approximately 6 million pregnant individuals annually and an unknown number of individuals facing a potential pregnancy or pregnancy risk due to sexual activity, contraceptive avoidance or failure, rape (including statutory rape), and incest. According to Federal data, 78 percent of sexually active females received reproductive health care in 2015-2017.[FN427]

The Department received comments related to the number of individuals affected by the rule, some of which are summarized below. One commenter asserted that the Department had overestimated the number of affected individuals and urged reducing the estimate to 78 percent of sexually active females (52.72 million). The same commenter also argued that even this revised number might be an overestimate, and that the number of individuals directly affected by the rule would be closer to 50,400 a year. Another commenter suggested that the number of individuals potentially affected by the proposed rule is much larger than the estimate and that the estimate should include any individual who was ever capable of bearing children and their family members.

Another commenter asserted that the Department was underestimating the number of individuals that would be affected by the proposed rule but did not include an estimate of their own.

After reviewing the comments, the Department is finalizing the estimates of the number of individuals that will be affected by this final rule as described above, which includes updates for 2022 data. The Department considers a key category of individuals affected by this final rule those who have the potential to become pregnant because pregnancies may occur and result in a need for reproductive health care nationwide. Pregnancy, concern about potential pregnancy, and the need for reproductive health care do not recognize state boundaries or regulatory timelines.

Commenters recommended data points above and below the Department's proposed estimate of 74 million affected individuals. We believe that the number of affected individuals is far greater than the total who are survivors of sexual assault or sex trafficking (as recommended by a commenter), yet less than the number of all individuals who have ever been of childbearing age and their family members (as recommended by another commenter). We recognize that the age range for the proposed estimate of females, 10-44, imperfectly reflects the number of females of childbearing age; however, the number of females over age 44 who could become pregnant may be offset by the number of females aged 10-13 who are not yet capable of childbearing.

We use the number of females of potentially childbearing age as a proxy for the number of individuals affected by the final rule as shown in Table 5 below.

Table 5—Estimated Number of Individuals Affected

Females of potentially childbearing age ⁴²⁸	Population estimate
10 to 14 years	10,327,799
15 to 19 years	10,618,136
20 to 24 years	10,957,463
25 to 29 years	10,762,368
30 to 34 years	11,440,546
35 to 39 years	11,013,337
40 to 44 years	10,771,942
Total	75,891,591

3. Costs of the Rule

Below, the Department provides the basis for its estimated quantifiable costs resulting from the changes to specific provisions of the Privacy Rule. Many of the estimates are based on assumptions formed through the Office for Civil Rights' (OCR's) experience with its compliance and enforcement program and accounts from stakeholders received at outreach events. The Department has quantified recurring burdens for this final rule for obtaining an attestation from a person requesting the use or disclosure of PHI potentially related to reproductive health care for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners or medical examiners.

The Department requested information or data points from commenters to further refine its estimates and assumptions. We examine the most substantive comments received in the cost section below. Additionally, we received comments that are also discussed below on topics that are not directly addressed in the cost section.

A commenter asserted that the Department did not account for the additional costs associated with major depressive disorders that would arise from the increase in abortions due to the rule. The Department does not believe that is a valid benchmark for the effects of this final rule, in part because we reject the premise, which is not backed by medical evidence or data, that this final rule will result in an increase in pregnancy terminations or depression.[FN429] Further, researchers have raised numerous concerns about the methodology of the 2011 study cited in ***33054** the comment.[FN430] Accordingly, we are not including the costs associated with treatment of depression in the cost section.

a. Costs Associated With Requests for Exception From Preemption

The Department anticipates that states with laws that restrict access to reproductive health care are likely to seek an exception to the requirements of this final rule that preempt state law. Given the pace at which state laws governing access to reproductive health care are changing, the Department is finalizing its proposed estimate that a potential increase of 26 states [FN431] will incur costs to develop a request to except a provision of state law from HIPAA's general preemption authority to submit to the Secretary.[FN432] Based on existing burden estimates for this activity,[FN433] the Department is finalizing its estimate that each exception request will require approximately 16 hours of labor at the rate of a general health care practitioner and that

approximately 26 states will make such requests. Thus, the Department estimates that states will spend a total of 416 hours requesting exception from preemption and monetize this as a one-time cost of \$38,705 [= 16 x 26 x \$93.04].

b. Estimated Costs From Adding a Requirement for an Attestation for Disclosures for Certain Purposes

Multiple commenters asserted that the projected attestation cost in the proposed rule was incorrect and underestimated the true cost of implementing the proposed requirement. One commenter asserted that the proposed rule underestimated the time to review medical records for PHI about reproductive health care and recommended that it be increased significantly. The same commenter also suggested that the Department adopt a requirement to obtain an individual's authorization, instead of an attestation, because it would reduce costs. Other commenters asserted that the proposed cost estimates for the attestation requirement did not account for associated administrative burdens, urged the Department to require an attestation for every request for PHI to decrease overall costs by establishing a procedural norm, or requested that the Department provide grants and trainings to regulated entities to offset the costs of the attestation provision. Finally, another commenter requested that the Department release a model attestation form to decrease the cost burden for covered entities.

A few commenters asserted that the Department mis-identified the types of staff that would performing specific components of the attestation requirement. One posited that both a lawyer and a medical professional would need to review medical records for the use or disclosure of PHI in response to the proposed revisions to the Privacy Rule. Another asserted that the person reviewing PHI in response to a request for the use or disclosure of PHI would be a medical records clerk.

The Department has modified the attestation requirement in response to public comments. As discussed above, this final rule requires regulated entities to obtain an attestation that the request for the use or disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii) when the request is for certain purposes (health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners and medical examiners) and is for PHI potentially related to reproductive health care. Where the request is for a purpose that implicates 45 CFR 164.502(a)(5)(iii) and the reproductive health care was provided by someone other than the regulated entity that received the request, such health care is presumed lawful under the circumstances in which it was provided unless the conditions of 45 CFR 164.502(a)(5)(iii)(C) are met. We expect the presumption of lawfulness to lower the burden for regulated entities to process requests for the use or disclosure of PHI for which an attestation is required; however, we also acknowledge that the proposed estimate did not fully represent the number of likely requests for the use or disclosure of PHI. The Department declines to require a valid authorization for these requests, as opposed to an attestation, and no grants to offset costs will be needed because of the lower estimated burden per request. The revised cost estimates include review of each request for the use or disclosure of PHI for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners and medical examiners, to determine if an attestation has been provided and administrative burdens associated with obtaining the attestation.

This final rule necessitates that regulated entities establish a process for responding to requests for the use or disclosure of PHI for which an attestation is required, such as reviewing and screening requests that are not accompanied by a valid authorization and are not a right of access request. We anticipate that across all regulated entities, this final rule will result in approximately 2,794,201 requests that regulated entities need to review in connection with the permissions under 45 CFR 164.512(d)-(g)(1). The Department estimates 5 minutes of average processing time per attestation based on the average wage of a mix of several occupations: medical and health services managers, medical records specialists, and health practitioners.[FN434] For example, a medical records specialist may forward certain requests for the use or disclosure of PHI (for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners and medical examiners) to a manager to review whether the request pertains to the lawfulness of reproductive health care. A health practitioner may review a number of records subject to a request for whether they contain PHI potentially related to reproductive health care. We calculate the annual cost for initial processing of the estimated 2,794,201 requests requiring attestations to total \$20,585,500 [2,794,201 x (5/60) x \$88.41]. For almost all of these requests, we believe that a brief review will be sufficient for a regulated entity to make a final disclosure determination.

For a small number of these requests, approximately 1,300, we assume that the brief review will not be sufficient; we assume that these requests will require legal review. This figure is an estimate of the number of requests that are generated to investigate or impose liability on a person for the mere act of seeking or obtaining lawful reproductive health care, including from a health care *33055 provider in a state other than the state where the regulated entity is located. The Department's estimate assumes that approximately 26 states may seek to restrict access to out-of-state reproductive health care, including reproductive health care that is lawful under the circumstances in which it provided, and will initiate an average of 50 such requests annually. The Department estimates on average 1 hour of review for such requests based on the wage of a lawyer.[FN435] We calculate the annual legal review cost for the estimated 1,300 requests totals \$204,724 [1,300 x 1 x \$157.48]. This additional review increases the cost of processing attestations to \$20,790,224.

We anticipate that approximately one-quarter of requests that result in legal reviews, approximately 325, will require additional managerial review by the regulated entity before making a disclosure decision. The Department estimates on average 3 hours of additional review for each of these requests based on the wage of medical and health insurance managers.[FN436] We calculate a total cost for additional actions for these requests of \$119,984 [325 x 3 x \$123.06]. The total annual estimated cost of processing attestations, including all additional legal and managerial reviews, is \$20,910,207.

Upon consideration of the estimated cost for regulated entities to create a new attestation form, the Department is planning to develop a model form to be available prior to the compliance date of this final rule. This will save an estimated total of \$60,970,823 [= 774,331 x (30/60) x \$157.48], based on 30 minutes of labor by a lawyer.

c. Costs Arising From Revised Business Associate Agreements

The Department anticipates that a certain percentage of business associate agreements will likely need to be updated to reflect a determination made by parties about their respective responsibilities when either party receives requests for disclosures of PHI under 45 CFR 164.512(d), (e), (f), or (g)(1). For example, each of the parties to the business associate agreement may need to notify the other party when they have knowledge that a request is for an unlawful purpose and allocate their respective responsibilities for handling these less frequent requests. The Department is finalizing its proposed estimate that each new or significantly modified contract between a business associate and its subcontractors will require, on average, one hour of labor by a lawyer at the wage reported in Table 3. We believe that approximately 35 percent of 1 million business associates, or 350,000 entities, will decide to create or significantly modify subcontracts, resulting in total costs of \$55,118,000 [= 350,000 x \$157.48].

A few commenters asserted that the Department's estimates for business associates' costs were incorrect and that it should consider additional costs. A commenter recommended that the Department adopt a non-enforcement period to allow business associates to achieve compliance and limit legal costs. Another commenter stated that the Department did not adequately identify the costs that would be associated with increased legal scrutiny of business associates as a result of the proposed rule. And another commenter urged the Department to consider the additional costs for renegotiated contracts as a result of the proposed rule. Lastly, a commenter requested that the Department apply the attestation requirement to business associates because it would reduce the costs of the rule.

The Department has reviewed the comments and is adopting the 2023 Privacy Rule NPRM cost analysis in this final rule. Business associate costs are adequately captured by the estimate for revising agreements. Applying costs directly to business associates (as opposed to covered entities) is distributional and will not alter the total impact of the rule. The Department declines to create an additional non-enforcement period for this provision of the final rule beyond the 180 days from the date of publication for the final rule to the compliance date.[FN437] The estimated cost for responding to requests for PHI for which an attestation is required accounts for increased scrutiny of a small number of requests for PHI, and the estimated costs for updating business associate agreements accounts for renegotiation of an average of one release of information vendor contract for nearly half of all covered entities.

d. Costs Arising From Changes to the Notice of Privacy Practices

The final rule modifies the NPP to notify individuals that covered entities cannot use or disclose PHI for certain purposes and that in certain circumstances, covered entities must obtain an attestation from a person requesting the PHI that affirms that the use or disclosure is not for a purpose prohibited under [45 CFR 164.502\(a\)\(5\)\(iii\)](#). The final rule also modifies the NPP to align with changes proposed in the 2022 Part 2 NPRM. This includes requiring covered entities that create or maintain Part 2 records to provide a notice that: addresses such records; references Part 2 as “other applicable law” that is more stringent than the Privacy Rule; explains that covered entities may not use or disclose a Part 2 record in a civil, criminal, administrative, or legislative proceeding against the individual absent written consent from the individual or a court order; and clarifies the applicability of Part 2 for organized health care arrangements that hold Part 2 records. Additionally, the final rule further modifies language for fundraising by covered entities that use or disclose Part 2 records to require a clear and conspicuous opt-out opportunity for patients. Finally, the modifications require the NPP to explain that PHI disclosed to a person other than a regulated entity is no longer subject to the requirements of the Privacy Rule.

The Department believes the burden associated with revising the NPP consists of costs related to developing and drafting the revised NPP for covered entities. The Department estimates that the updating and revising the language in the NPP will require 50 minutes of professional legal services at the wage reported in Table 3. Across all covered entities, the Department estimates a cost of \$101,618,038 [= 774,331 x (50/60) x \$157.48]. The Department does not anticipate any new costs for health care providers associated with distribution of the revised notice other than posting it on the entity's website (if it has one) because health care providers have an ongoing obligation to provide the notice to first-time patients that is already accounted for in cost estimates for the HIPAA Rules. Health plans that post their NPP online will incur minimal costs by posting the updated notice and then including the updated NPP in the next annual mailing to subscribers.[FN438] Health plans that do not provide an annual mailing will potentially incur an additional \$12,743,700 in capital expenses for mailing the revised NPP to an estimated 10 percent of the 150,000,000 health plan subscribers who receive a mailed, paper copy of the notice, as well as the labor expense for an administrative support staff member at the rate shown in Table 3 to complete the mailing, for approximately \$2,737,500 [= 62,500 hours x \$43.80]. The Department further estimates the cost of posting the revised NPP on the ***33056** covered entity's website will be 15 minutes of a web designer's time at the wage reported in Table 3. Across all covered entities, the Department estimates a cost of online posting as \$18,936,265 [= 774,331 x (15/60) x \$97.82].

A commenter expressed concern that the Department was underestimating the cost of mailing updates associated with changes to NPP policies.

The Department is already accounting for the cost of mailing updated NPPs within the estimated capital costs, which include printing copies of NPPs that are provided in person and those that are mailed, and postage for health plans that will need to conduct a mailing that is off-cycle from its regular schedule. We estimate that half of NPPs will need to be mailed and that health plans may include the updated NPP with their next regular mailing to individuals.

e. Estimated Costs for Developing New or Modified Policies and Procedures

The Department anticipates that covered entities will need to develop new or modified policies and procedures for the new requirements for attestations, the new category of prohibited uses and disclosures, modifications to certain uses and disclosures permitted under [45 CFR 164.512](#), and clarification of personal representative qualifications. The Department is finalizing its proposed estimate that the costs associated with developing such policies and procedures will be the labor of a lawyer for 2.5 hours and that this expense represents the largest area of cost for compliance with this final rule, for a total of \$304,854,115 [= 774,331 x 2.5 x \$157.48].

A few commenters stated that the estimate for covered entities to draft new policies was incorrect and provided additional information or alternatives to reduce costs. A commenter stated that the time burden for drafting new policies was insufficient and did not accurately represent the amount of time it would take a covered entity to draft a policy that complied with the proposed rule. Another commenter urged the Department to include the costs for organizations to update their privacy policies because of the proposed rule. A few commenters requested that the Department provide organizations with additional time to develop new policies that comply with the final rule.

The Department considered the concerns raised by commenters about the burdens of the requirements to revise the Privacy Rule and made several additional modifications in this final rule to reduce burdens on regulated entities. For example, regulated entities are not required to develop policies to routinely evaluate whether reproductive health care that was provided by someone else was lawful. Instead, regulated entities will need to develop policies to ensure that regulated entities identify requests for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners or medical examiners and procedures for obtaining the required attestation if it is not provided with the request for the use or disclosure of PHI. Additional policies will be required to address requests for the above purposes that could result in a prohibited use or disclosure, such as requests from law enforcement for the use or disclosure of PHI that assert, without any other information, that reproductive health care was provided unlawfully. The updating of privacy policies is included in the overall cost of updating policies and the estimate for updating the NPP. Because of changes in the final rule that simplify compliance with the new requirements, the Department is not adjusting the time burden for revising or creating new policies and procedures.

f. Costs Associated With Training Workforce Members

The Department anticipates that covered entities will be able to incorporate new content into existing HIPAA training requirements and that the costs associated with doing so will be attributed to the labor of a training specialist for an estimated 90 minutes for a total of \$78,029,335 [= 774,331 x (90/60) x \$67.18].

A few commenters addressed training costs within the proposed rule, including one who asserted that such costs could be reduced by ensuring that the effective date for all of the provisions of the rule is the same. Another commenter stated that covered entities would incur both a one time and yearly training cost, with the yearly training cost accounting for most of the total training cost in year 1.

The Department is finalizing the cost estimate for training workforce members as proposed, which includes the cost of a training a specialist to update the covered entity's HIPAA training program with new content to include in training for workforce members within the first year. Any further recurring component is likely to be implemented into regularly scheduled employee training and will thus not be directly attributable to this rule.

g. Total Quantifiable Costs

The Department summarizes in Table 6 the estimated nonrecurring costs that covered entities and states will experience in the first year of implementing the regulatory changes. The Department anticipates that these costs will be for requesting exceptions from preemption of contrary state law, implementing the attestation requirement, revising business associate agreements, revising the NPP, mailing and posting it online, revising policies and procedures, and updating HIPAA training programs.

Table 6—New Nonrecurring Costs of Compliance With the Final Rule

Nonrecurring costs	Burden hours/ action x hourly wage	Respondents	Total costs (millions)
Exception Requests	16 x \$93.04	26 States	\$0.04
BA Agreements, Revising	1 x \$157.48	350,000 BAAs	55
NPP, Updating	50/60 x \$157.48	774,331 Covered entities	102

NPP, Mailing	0.25/60 x \$43.80	15,000,000 Subscribers	3
NPP, Posting Online	15/60 x \$97.82	774,331 Covered entities	19
Policies & Procedures	150/60 x \$157.48	774,331 Covered entities	305
Training	90/60 x \$67.18	774,331 Covered entities	78
Capital Expenses, Mailing NPPs— Health Plans	\$.85/NPP	15,000,000 Subscribers	13
Total Nonrecurring Burden ^a 574		

***33057** Table 7 summarizes the recurring costs that the Department anticipates covered entities will incur annually as a result of the regulatory changes. These new costs are based on responding to requests for uses and disclosures of PHI that are conditioned upon an attestation.

Table 7—Recurring Annual Costs of Compliance With the Final Rule^a

Recurring costs	Burden hours x wage	Respondents	Total annual cost (millions)
Disclosures for which an attestation is required	232,850 x \$88.41	2,794,201	\$20,585,500
Attestation investigation review	1,300 x \$157.48	1,300	204,724
Attestation additional actions	975 x 123.06	325	119,984
Total Recurring Annual Burden		20,910,207

Costs Borne by the Department

The covered entities that are operated by the Department will be affected by the changes in a similar manner to other covered entities, and such costs have been factored into the estimates above.

The Department expects that it will incur costs related to drafting and disseminating a model attestation form and information about the regulatory changes to covered entities, including health care providers and health plans. In addition, the Department anticipates that it may incur a 26-fold increase in the number of requests for exceptions from preemption of contrary state law in the first year after a final rule becomes effective, at an estimated total cost of approximately \$146,319 to analyze and develop responses for an average cost of \$7,410 per request. This increase is based on the number of states that have enacted or are likely to enact laws restricting access to reproductive health care [FN439] and may seek to obtain individuals' PHI to enforce those laws. This estimate assumes that the Department receives and reviews exception requests from the 26 states, that half require a more complex analysis, and that all requests result in a written response within one year of the final rule's publication.

Benefits of the Final Rule

The benefits of this final rule to individuals and families are likely substantial, and yet are not fully quantifiable because the area of health care this final rule addresses is among the most sensitive and life-altering if privacy is violated. Additionally, the value of privacy, which cannot be recovered once lost, and trust that privacy will be protected by others, is difficult to quantify fully. Health privacy has many significant benefits, such as promoting effective communication between individuals and health care

providers, preventing discrimination, enhancing autonomy, supporting medical research, and protecting the individual from unwanted exposure of sensitive health information.[FN440]

Notably, reproductive health care may include circumstances resulting in a pregnancy, considerations concerning maternal and fetal health, family genetic conditions, information concerning sexually transmitted infections, and the relationship between prospective parents (including victimization due to rape, incest, or sex trafficking). Involuntary or poorly-timed disclosures can irreparably harm relationships and reputations, and even result in job loss or other negative consequences in the workplace, [FN441] as well as investigation, civil litigation or proceedings, and prosecution for lawful activities.[FN442] Additionally, fear of potential penalties or liability that may result from disclosing information to a health care provider about accessing reproductive health care may cast a long shadow, decreasing trust between individuals and health care providers, discouraging and deterring access to other valuable and necessary health care, or compromising ongoing or subsequent care if an individual's medical records are not accurate or complete.[FN443] This final rule will prevent or reduce the harms discussed here, resulting in non-quantifiable benefits to individuals and their families, friends, and health care providers. In particular, the role of trust in the health care system and its importance to the provision of high-quality health care is discussed extensively in Section III of this preamble.

The Department anticipates that this final rule will increase health literacy by improving access to complete information about health care options for individuals.[FN444] For example, the prohibition on the use and disclosure of PHI for purposes of investigating or imposing liability on an individual, a person assisting them, or their health care provider for lawful health care will increase individuals' access to complete information about their health care options because they will have increased confidence to share information about their life, including their health, with health care providers. In turn, the receipt of more complete information from patients will enable ***33058** health care providers to provide more accurate and relevant medical information about lawful reproductive health care, and the new prohibition will enable them to do so without fear of serious and costly professional repercussions.

This final rule will also contribute to increased access to prenatal health care at the critical early stages of pregnancy by affording individuals the assurance that they may obtain lawful reproductive health care without fearing that records related to that care would be subject to disclosure. For example, if a sexually active individual fears they or their health care providers could be subject to prosecution as a result of disclosure of their PHI, the individual may avoid informing health care providers about symptoms or asking questions of medical experts and may consequently fail to receive necessary support and health care for a pregnancy diagnosis.[FN445] Similarly, this final rule will likely contribute to a decreased rate of maternal mortality and morbidity by improving access to information about health services.[FN446]

Additionally, this final rule will enhance the mental health and emotional well-being of individuals seeking or obtaining lawful reproductive health care by reducing fear that their PHI will be disclosed to investigate or impose liability on the individual, their health care provider, or any persons facilitating the individual's access to lawful reproductive health care. This is especially important for individuals who need access to reproductive health care because they are survivors of rape, incest, or sex trafficking. For at least some such individuals, certain types of reproductive health care, including abortion, often remain legal even if pregnancy termination is not available to the broader population under state law. The Department expects that this final rule will help to prevent or reduce re-victimization of pregnant individuals who have been subject to rape, incest, or sex trafficking by protecting their PHI from disclosure.

Activities conducted to investigate and impose liability that rely on that information may be costly to defend against and thus are financially draining for the target of those activities and for persons who are not the target of the activity but whose information may be used as evidence against others. Witnesses or targets of such activities may lose time from work and incur steep legal bills that create unmanageable debt or otherwise harm the economic stability of the individual, their family, and their health care provider. In the absence of this final rule, much of the costs may be for defending against the unwanted use or disclosure of PHI. Thus, the Department expects that this final rule will contribute to families' economic well-being by reducing the risk of exposure to costly activities to investigate or impose liability on persons for lawful activities as a result of disclosures of PHI.

This final rule will also contribute to improved continuity of care and ongoing and subsequent health care for individuals, thereby improving health outcomes. If a health care provider believes that PHI is likely to be disclosed without the individual's or the health care provider's knowledge or consent, possibly to initiate or be used in criminal or civil proceedings against the individual, their health care provider, or others, the health care provider is more likely to omit information about an individual's medical history or condition, leave gaps, or include inaccuracies when preparing the individual's medical records. And if an individual's medical records lack complete information about the individual's health history, a subsequent health care provider may not be able to conduct an appropriate health assessment to reach a sound diagnosis and recommend the best course of action for the individual. Alternatively, health care providers may withhold from the individual full and complete information about their treatment options because of liability concerns stemming from fears about the privacy of an individual's PHI.[FN447] Heightened confidentiality and privacy protections enable a health care provider to feel confident maintaining full and complete patient records. Without complete patient records, an individual is less likely to receive appropriate ongoing or future health care, including correct diagnoses, and will be impeded in making informed treatment decisions.

Comparison of Benefits and Costs

A few commenters stated that the 2023 Privacy Rule NPRM reflected the staffing costs of covered entities in full. One posited that covered entities will receive more requests for PHI because of changes in the legal environment after Dobbs, which will require some regulated entities that may not typically get such requests to adjust according to the changes in the law and how it is enforced. Another commenter stated that the proposed rule did not account for higher staffing costs from more highly qualified employees. The commenters did not provide any relevant data or discussion of methodology for how these costs should be quantified. Therefore, the Department did not include any additional labor costs in the economic analysis based on this comment.

A few additional commenters expressed general concerns related to electronic health record (EHR) systems and data storage. One urged the Department to include costs associated with updating EHR systems to ensure compliance and to allow for data segmentation. Another asserted that the current classifications for different types of PHI are not clear enough for effective data segmentation, contributing to increased costs. As a result, they recommended that the Department provide clearer guidelines on the different types of PHI. The Department did not attempt to estimate additional data maintenance or EHR-related costs because any adjustments will be part of the regular cost of business for regulated entities.

A commenter stated that the Department did not quantify the costs associated with violations of the rule by regulated entities, such as incurring a monetary penalty after impermissibly responding to a court order. The Department does not quantify the costs of noncompliance as part of its analysis. Whether a violation will result in a monetary penalty is dependent on numerous factors and the aim of the Department's enforcement is to bring regulated entities into compliance.

A few commenters asserted that the proposed rule would make it more difficult for law enforcement to investigate criminals for crimes related to sex and recommended that the Department quantify this cost. The Department acknowledges that the final rule may result in some changes to procedures for handling law enforcement requests for PHI; however, the burden on regulated entities is calculated in its cost estimates. The Department is unable to quantify the burdens to law enforcement resulting from this final rule. However, to address concerns about victims' ability to disclose their PHI related to reproductive health care, the final rule ***33059** permits individuals to authorize disclosures for any purpose, including law enforcement investigations. Therefore, the Department is not including costs to law enforcement in the quantified costs and benefits analysis. The Department expects the totality of the benefits of this final rule to outweigh the costs, particularly in light of the privacy benefits for individuals who could become pregnant (nearly one-fourth of the U.S. population in any given year) and seek access to lawful health care without the risk of their PHI being used or disclosed in furtherance of activities to conduct criminal, civil, or administrative investigations or impose liability without their authorization. The Department expects covered entities and individuals to benefit from covered entities' increased confidence to be able to provide lawful health care according to professional standards.

The Department's qualitative benefit-cost analysis asserts that the regulatory changes in this final rule will support an individual's privacy with respect to lawful health care, enhance the relationship between health care providers and individuals, strengthen maternal well-being and family stability, and support victims of rape, incest, and sex trafficking. The regulatory changes will also aid health care providers in developing and maintaining a high level of trust with individuals and maintaining complete and accurate medical records to aid ongoing and subsequent health care. Greater levels of trust will further enable individuals to develop and maintain relationships with health care providers, which would enhance continuity of health care for all individuals receiving care from the health care provider, not only individuals in need of reproductive health care.

The financial costs of this final rule will accrue primarily to covered entities, particularly health care providers and health plans in the first year after implementation of a final rule, with recurring costs accruing annually at a lower rate.

B. Regulatory Alternatives to the Final Rule

In addition to regulatory proposals in the 2023 Privacy Rule NPRM that are not adopted here, the Department considered several alternatives to the policies finalized in this rule.

Define Public Health in the Context of Public Health Surveillance, Intervention, or Investigation

The Department considered alternatives to the proposed definition of “public health” in the context of public health surveillance, investigation, and intervention, particularly the reference to population-level activities. Specifically, the Department considered whether to add “individual-level” to further distinguish public health surveillance, investigation, and intervention from other activities but did not adopt this approach because it would add a new undefined term that would generate more complexity without adding clarity. The Department also considered removing “population-level” from the definition in this final rule, but we are not adopting that approach because it might lead people to believe that the focus of public health is not on activities benefiting the population as a whole. Additionally, the Department considered defining “public health” surveillance, investigation, or intervention only in the negative—that is, by listing activities that are excluded—but decided not to adopt this approach to ensure that stakeholders understand what public health surveillance, investigation, or intervention means.

Modify Prohibition To Presume That Reproductive Health Care Is Lawful Absent Actual Knowledge

The Department considered adding a provision that would allow regulated entities to presume that certain requests for PHI are about reproductive health care that was lawful under the circumstances in which such health care was provided where it was provided by someone other than the regulated entity receiving the PHI request, unless the regulated entity had actual knowledge that such health care was not lawful under the circumstances in which it was provided. However, in consultation with Federal partners, the Department decided to finalize a second exception to the presumption to permit uses or disclosures of PHI where privacy interests are reduced, as compared to the societal interest in the PHI for certain non-health care purposes. This exception is available where factual information supplied by the person requesting the use or disclosure of PHI demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided.

Administrative Requests by Law Enforcement

The Department received reports that not all regulated entities are interpreting the administrative request provision correctly and proposed a clarification to [45 CFR 164.512\(f\)\(1\)\(ii\)\(C\)](#). To address concerns that disclosures currently made under Federal agencies' interpretations of the Privacy Act of 1974 [FN448] would not be permitted under the NPRM proposal, the Department considered adding qualifying language to paragraph [45 CFR 164.512\(f\)\(1\)\(ii\)\(C\)](#) to state that PHI may be disclosed by a Federal agency in response to an administrative request from law enforcement where the Federal agency is authorized, but not required, to disclose under applicable law (see, e.g., the Privacy Act and OMB 1975 Guidelines [FN449]). However, the Department determined that the contemplated change was not necessary because the intent of the Privacy Rule was adequately captured in the clarification proposed in the NPRM and finalized in this rule at [45 CFR 164.512\(f\)\(1\)\(ii\)\(C\)](#). As finalized, this provision

permits disclosures to law enforcement in response to “an administrative request for which response is required by law, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law.”

Scope of Prohibited Conduct

In response to public comments on the 2023 Privacy Rule NPRM, the Department considered several approaches to outlining prohibited conduct. One approach was creating a category of “highly sensitive PHI” and prohibiting its use and disclosure in certain proceedings based on the mere act of, for example, obtaining, providing, or aiding that category of health care. The Department did not adopt this category based on many concerns expressed in public comments. For example, distinguishing between the sensitivity of different types of PHI would require complicated subjective determinations, and prohibiting or limiting uses or disclosures of highly sensitive PHI for certain purposes could negatively affect efforts to eliminate data segmentation and further stigmatize the types of health care included in the “highly sensitive” category.

Another approach the Department considered was to require an attestation for all requested uses and disclosures of PHI under 45 CFR 164.512(d)-(g)(1), rather than limiting the requirement to only requested uses and disclosures of PHI potentially related to reproductive health care under such provisions. This would have reduced the burden on *33060 regulated entities to screen requested PHI for whether it contained information potentially related to reproductive health care and increased the burden on persons requesting PHI to evaluate and attest to all requests for use and disclosure of PHI under 45 CFR 164.512(d)-(g)(1). However, in recognition of the importance of oversight and law enforcement entities' ability to obtain PHI for legitimate inquiries, the Department decided not to require an attestation for all requests under these provisions.

Requiring an Attestation Under Penalty of Perjury

The Department requested comments about the possibility of adding a required penalty of perjury statement to strengthen the attestation requirement but did not propose this statement in the 2023 Privacy Rule NPRM. After reviewing public comments on this topic, the Department considered adding a requirement that the attestation be signed by the person requesting the use or disclosure of PHI under penalty of perjury but did not adopt such a requirement in the final rule. As discussed in greater detail above, a person who knowingly and in violation of the Administrative Simplification provisions of HIPAA obtains or discloses IIHI relating to another individual or discloses IIHI to another person is subject to criminal liability.[FN450] Thus, a person who knowingly and in violation of HIPAA [FN451] falsifies an attestation (e.g., makes material misrepresentations about the intended uses of the PHI requested) to obtain (or cause to be disclosed) an individual's IIHI could be subject to criminal penalties as outlined in the statute. The Department believes such penalties are sufficient to hold persons who knowingly submit false attestations accountable for their actions and deter such submissions entirely.

Right To Request Restrictions

In the 2023 Privacy Rule NPRM, the Department requested comments regarding the right of individuals to request restrictions of uses and disclosures of their PHI. We did not propose any changes to this provision in the 2023 Privacy Rule NPRM, nor are we proposing or finalizing any modifications to it at this time. We appreciate the comments we received regarding expanding the rights to request disclosures and will take them under advisement when we consider future modifications to the Privacy Rule.

C. Regulatory Flexibility Act—Small Entity Analysis

The Department has examined the economic implications of this final rule as required by the RFA. If a rule has a significant economic impact on a substantial number of small entities, the RFA requires agencies to analyze regulatory options that would reduce the economic effect of the rule on small entities.

For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The Act defines “small entities” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, and (3) a small government jurisdiction of less than 50,000

population. A few commenters raised concerns about the effects of the proposed rule on small or rural providers and requested additional analysis, guidance, or technical assistance from the Department to aid these entities. The Department did not receive any public comments on the small business analysis assumptions used in the NPRM. Accordingly, we are not changing the baseline assumptions for this final rule. We have updated our analysis of small entities for consistency with revisions to the RIA for the costs and savings for covered entities. The Department has determined that roughly 90 percent or more of all health care providers meet the SBA size standard for a small business or are a nonprofit organization. Therefore, the Department estimates that there are 696,898 small entities affected by the final rule.[FN452] The SBA size standard for health care providers ranges between a maximum of \$16 million and \$47 million in annual receipts, depending upon the type of entity.[FN453]

With respect to health insurers, the SBA size standard is a maximum of \$47 million in annual receipts, and for third party administrators it is \$45.5 million.[FN454] While some insurers are classified as nonprofit, it is possible they are dominant in their market. For example, a number of Blue Cross/Blue Shield insurers are organized as nonprofit entities; yet they dominate the health insurance market in the states where they are licensed.[FN455]

For the reasons stated below, we do not expect that the cost of compliance will be significant for small entities. Nor do we expect that the cost of compliance will fall disproportionately on small entities. Although many of the covered entities affected by this final rule are small entities, they will not bear a disproportionate cost burden compared to the other entities subject to the rule. The projected total costs are discussed in detail in the RIA. The Department does not view this as a substantial burden because the result of the changes will be annualized costs per covered entity of approximately \$184 [= \$142.6 million [FN456]/774,331 covered entities]. In the context of the RFA, HHS generally considers an economic impact exceeding 3 percent of annual revenue to be significant, and 5 percent or more of the affected small entities within an identified industry to represent a substantial number. The quantified impact of \$184 per covered entity would only apply to covered entities whose annual revenue is \$6,133 or less. We believe almost all, if not all covered entities have annual revenues that exceed this amount. Accordingly, the Department has determined that this final rule is unlikely to affect a substantial number of small entities that meet the RFA threshold. Thus, this analysis concludes, and the Secretary certifies, that the rule will not result in a significant economic effect on a substantial number of small entities.

D. Executive Order 13132—Federalism

As required by E.O. 13132 on Federalism, the Department has examined the provisions in both the proposed and final regulation for their effects on the relationship between the Federal Government and the states. In the Department's view, the final regulation may have federalism implications because it may have direct effects on the states, the relationship between the Federal Government and states, and on the distribution of power and responsibilities among various *33061 levels of government relating to the disclosure of PHI.

The changes from this final rule flow from and are consistent with the underlying statute, which authorizes the Secretary to issue regulations that govern the privacy of PHI. The statute provides that, with limited exceptions, such regulations supersede contrary provisions of state law unless the provision of state law imposes more stringent privacy protections than the Federal law.[FN457]

Section 3(b) of E.O. 13132 recognizes that national action limiting the policymaking discretion of states will be imposed only where there is constitutional and statutory authority for the action and the national activity is appropriate when considering a problem of national significance. The privacy of PHI is of national concern by virtue of the scope of interstate health commerce. As described in the preamble to the proposed rule and this final rule, recent state actions affecting reproductive health care have undermined the longstanding expectation among individuals in all states that their highly sensitive reproductive health information will remain private and not be used against them for seeking or obtaining legal health care. These state actions thus directly threaten the trust that is essential to ensuring access to, and quality of, lawful health care. HIPAA's provisions reflect this position by authorizing the Secretary to promulgate regulations to implement the Privacy Rule.

Section 4(a) of E.O. 13132 expressly contemplates preemption when there is a conflict between exercising state and Federal authority under a Federal statute. Section 4(b) of the E.O. authorizes preemption of state law in the Federal rulemaking context when “the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.” The approach in this regulation is consistent with the standards in the E.O. because it supersedes state authority only when such authority is inconsistent with standards established pursuant to the grant of Federal authority under the statute.

State and local laws that impinge on the privacy protections for PHI of individuals who obtain lawful reproductive health care undermine Congress' directive to develop a health information system for the purpose of improving the effectiveness of the health care system, which requires that all individuals who receive health care legally are assured a minimum level of privacy for their PHI. Congress established specific, narrow exceptions to preemption that did not include the use or disclosure of an individual's medical records for law enforcement purposes generally. Nor did Congress include a specific exception to preemption that would permit states to use PHI against that individual, health care providers, or third parties merely for seeking, obtaining, providing, or facilitating lawful health care.[FN458] Both the personal and public interest is served by protecting PHI so as not to undermine an individual's access to and quality of lawful health care services and their trust in the health care system.

The Department anticipates that the most significant direct costs on state and local governments would be the cost for state and local government-operated covered entities to revise business associate agreements, revise policies and procedures, update the NPP, update training programs, and process requests for disclosures for which an attestation is required. These costs would be similar in kind to those borne by non-government operated covered entities. In addition, the Department anticipates that approximately half of the states may choose to file a request for an exception to preemption. The longstanding regulatory provisions that govern preemption exception requests under the HIPAA Rules would remain undisturbed by this rule.[FN459] However, based on the legal developments in some states that are described elsewhere in this preamble, the Department anticipates that in the first year of implementation of a final rule, more states will submit requests for exceptions from preemption than have done so in the past. The RIA above addresses these costs in detail.

Pursuant to the requirements set forth in section 8(a) of E.O. 13132, and by the signature affixed to the final rule, the Department certifies that it has complied with the requirements of E.O. 13132, including review and consideration of comments from state and local government officials and the public about the interaction of this rule with state activity, for the final rule in a meaningful and timely manner.

E. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 [FN460] requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. This final rule is expected to strengthen the stability of the family and marital commitment because it protects individual privacy in the context of sensitive decisions about family planning. The rule may be carried out only by the Federal Government because it would modify Federal health privacy law, ensuring that American families have confidence in the privacy of their information about lawful reproductive health care, regardless of the state where they are located when health care is provided. Such health care privacy is vital for individuals who may become pregnant or who are capable of becoming pregnant.

F. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 [FN461] (PRA), agencies are required to submit to OMB for review and approval any reporting or record-keeping requirements inherent in a proposed or final rule and are required to publish such proposed requirements for public comment. To fairly evaluate whether an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that the Department solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;

2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The PRA requires consideration of the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section. The Department considered public comments on its assumptions and burden estimates in the 2023 Privacy Rule NPRM and addresses those comments above in the discussion of benefits and costs of this final rule.

In this RIA, the Department is revising certain information collection requirements associated with this final rule and, as such, is revising the information collection last prepared in *33062 2023 and approved under OMB control #0945-0003. The revised information collection describes all new and adjusted information collection requirements for covered entities pursuant to the implementing regulation for HIPAA at 45 CFR parts 160 and 164, the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules ("HIPAA Rules").

The estimated annual labor burden presented by the regulatory modifications in the first year of implementation, including nonrecurring and recurring burdens, is 4,584,224 burden hours at a cost of \$582,242,165 [FN462] and \$20,910,207 of estimated annual labor costs in years two through five. The overall total burden for respondents to comply with the information collection requirements of all of the HIPAA Privacy, Security, and Breach Notification Rules, including nonrecurring and recurring burdens presented by program changes, is 953,982,236 burden hours at a cost of \$107,336,705,941, plus \$197,364,010 in capital costs for a total estimated annual burden of \$107,534,069,951 in the first year following the effective date of the final rule. Details describing the burden analysis for the proposals associated with this RIA are presented below and explained further in the ICR associated with this final rule.

Explanation of Estimated Annualized Burden Hours

Below is a summary of the significant program changes and adjustments made since the approved 2023 ICR; because the ICR addresses regulatory burdens associated with the full suite of HIPAA Rules, the changes and adjustments include updated data and estimates for some provisions of the HIPAA Rules that are not affected by this final rule. These program changes and adjustments form the bases for the burden estimates presented in the ICR associated with this RIA.

Adjusted Estimated Annual Burdens of Compliance

- (1) Increasing the number of covered entities from 700,000 to 774,331 based on program change.
- (2) Increasing the number of respondents requesting exceptions to state law preemption from 1 to 27 based on an expected reaction by states that have enacted restrictions on reproductive health care access.
- (3) Increasing the burden hours by a factor of two for responding to individuals' requests for restrictions on disclosures of their PHI under [45 CFR 164.522](#) to represent a doubling of the expected requests.
- (4) Updating the number of breaches for which notification is required to reflect data in OCR's 2022 Report to Congress [FN463] and related burdens.
- (5) Increasing the number of estimated uses and disclosures for research purposes.
- (6) Increasing the total number of NPPs distributed by health plans by 50% to total 300,000,000 due to the increase in number of Americans with health coverage.

New Burdens Resulting from Program Changes

In addition to these changes, the Department added new annual burdens as a result of program changes in the final rule:

- (1) A nonrecurring burden of 1 hour for each of 350,000 business associate agreements that is likely to be revised as a result of the changes to handling requests for PHI under [45 CFR 164.512\(d\), \(e\), \(f\), and \(g\)\(1\)](#), to allocate responsibilities between covered entities and their release-of-information contractors.
- (2) A recurring burden of 5 minutes per request for staff to determine whether an attestation is required for disclosure under [45 CFR 164.509](#).
- (3) A recurring burden of 1 hour per request for legal review of whether certain requests identified by staff as potentially requiring an attestation pertain to the lawfulness of reproductive health care.
- (4) A recurring burden of 3 hours per request for a percentage of requests requiring legal review that might require additional manager review to determine whether the requirements at [45 CFR 164.509](#) are met.
- (5) A nonrecurring burden of 50 minutes per covered entity to update the required content of its NPP.
- (6) A nonrecurring burden of 15 minutes per covered entity for posting an updated NPP online.
- (7) A nonrecurring burden of 2.5 hours for each covered entity to update its policies and procedures.
- (8) A nonrecurring burden of 90 minutes for each covered entity to update the content of its HIPAA training program.

List of Subjects

45 CFR Part 160

Health care, Health records, Preemption, Privacy, Public health, Reproductive health care.

45 CFR Part 164

Health care, Health records, Privacy, Public health, Reporting and recordkeeping requirements, Reproductive health care.

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter C, parts 160 and 164 as set forth below:

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 160 continues to read as follows:

Authority: [42 U.S.C. 1302\(a\)](#); [42 U.S.C. 1320d-1320d-9](#); sec. 264, [Pub. L. 104-191](#), [110 Stat. 2033-2034](#) ([42 U.S.C. 1320d-2 \(note\)](#)); [5 U.S.C. 552](#); secs. 13400-13424, [Pub. L. 111-5](#), [123 Stat. 258-279](#); and sec. 1104 of [Pub. L. 111-148](#), [124 Stat. 146-154](#).
[45 CFR § 160.103](#)

2. Amend [§ 160.103](#) by:

- a. Revising the definition of “Person”; and
- b. Adding in alphabetical order the definitions of “Public health” and “Reproductive health care”.

The revision and additions read as follows:

[45 CFR § 160.103](#)

§ 160.103 Definitions.

* * * * *

Person means a natural person (meaning a human being who is born alive), trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

* * * * *

Public health, as used in the terms “public health surveillance,” “public health investigation,” and “public health intervention,” means population-level activities to prevent disease in and promote the health of populations. Such activities include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information. But such activities do not include those with any of the following purposes:

(1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating health care.

(2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care.

***33063** (3) To identify any person for any of the activities described at paragraphs (1) or (2) of this definition.

Reproductive health care means health care, as defined in this section, that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes. This definition shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care.

* * * * *

PART 164—SECURITY AND PRIVACY

3. The authority citation for part 164 continues to read as follows:

Authority: [42 U.S.C. 1302\(a\)](#); [42 U.S.C. 1320d-1320d-9](#); sec. 264, [Pub. L. 104-191](#), 110 Stat. 2033-2034 ([42 U.S.C. 1320d-2\(note\)](#)); and secs. 13400-13424, [Pub. L. 111-5](#), 123 Stat. 258-279.

[45 CFR § 164.502](#)

4. Amend [§ 164.502](#) by

- a. Revising paragraph (a)(1)(vi);
- b. Adding paragraph (a)(5)(iii); and
- c. Revising paragraph (g)(5).

The addition and revisions read as follows:

[45 CFR § 164.502](#)

§ 164.502 Uses and disclosures of protected health information: General rules.

(a) * * *

(1) * * *

(vi) As permitted by and in compliance with any of the following:

(A) This section.

(B) [Section 164.512](#) and, where applicable, [§ 164.509](#).

(C) [Section 164.514\(e\)](#), (f), or (g).

* * * * *

(5) * * *

(iii) Reproductive health care—(A) Prohibition. Subject to paragraphs (a)(5)(iii)(B) and (C) of this section, a covered entity or business associate may not use or disclose protected health information for any of the following activities:

(1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

(2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

(3) To identify any person for any purpose described in paragraphs (a)(5)(iii)(A)(1) or (2) of this section.

(B) Rule of applicability. The prohibition at paragraph (a)(5)(iii)(A) of this section applies only where the relevant activity is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care, and the covered entity or business associate that received the request for protected health information has reasonably determined that one or more of the following conditions exists:

(1) The reproductive health care is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided.

(2) The reproductive health care is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided.

(3) The presumption at paragraph (a)(5)(iii)(C) of this section applies.

(C) Presumption. The reproductive health care provided by another person is presumed lawful under paragraph (a)(5)(iii)(B) (1) or (2) of this section unless the covered entity or business associate has any of the following:

(1) Actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided.

(2) Factual information supplied by the person requesting the use or disclosure of protected health information that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided.

(D) Scope. For the purposes of this subpart, seeking, obtaining, providing, or facilitating reproductive health care includes, but is not limited to, any of the following: expressing interest in, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, administering, authorizing, providing coverage for, approving, counseling about, assisting, or otherwise taking action to engage in reproductive health care; or attempting any of the same.

* * * * *

(g) * * *

(5) Implementation specification: Abuse, neglect, endangerment situations. Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative, provided that the conditions at paragraphs (g)(5)(i) and (ii) of this section are met:

(i) Paragraphs (g)(5)(i)(A) and (B) of this section both apply.

(A) The covered entity has a reasonable belief that any of the following is true:

(1) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person.

(2) Treating such person as the personal representative could endanger the individual.

(B) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(ii) The covered entity does not have a reasonable belief under paragraph (g)(5)(i)(A) of this section if the basis for their belief is the provision or facilitation of reproductive health care by such person for and at the request of the individual.

* * * * *45 CFR § 164.509

5. Add § 164.509 to read as follows:

45 CFR § 164.509

§ 164.509 Uses and disclosures for which an attestation is required.

(a) Standard: Attestations for certain uses and disclosures of protected health information to persons other than covered entities or business associates. (1) A covered entity or business associate may not use or disclose protected health information potentially related to reproductive health care for purposes specified in § 164.512(d), (e), (f), or (g)(1), without obtaining an attestation that is valid under paragraph (b)(1) of this section from the person requesting the use or disclosure and complying with all applicable conditions of this part.

(2) A covered entity or business associate that uses or discloses protected health information potentially related to reproductive health care for purposes specified in § 164.512(d), (e), (f), or (g)(1), in reliance on an attestation that is defective under paragraph (b)(2) of this section, is not in compliance with this section.

(b) Implementation specifications: General requirements—(1) Valid attestations. (i) A valid attestation is a document that meets the requirements of paragraph (c)(1) of this section.

(ii) A valid attestation verifies that the use or disclosure is not otherwise prohibited by § 164.502(a)(5)(iii).

(iii) A valid attestation may be electronic, provided that it meets the requirements in paragraph (c)(1) of this section, as applicable.

(2) Defective attestations. An attestation is not valid if the document submitted has any of the following defects:

(i) The attestation lacks an element or statement required by paragraph (c) of this section.

(ii) The attestation contains an element or statement not required by paragraph (c) of this section

(iii) The attestation violates paragraph (b)(3) of this section.

***33064** (iv) The covered entity or business associate has actual knowledge that material information in the attestation is false.

(v) A reasonable covered entity or business associate in the same position would not believe that the attestation is true with respect to the requirement at paragraph (c)(1)(iv) of this section.

(3) Compound attestation. An attestation may not be combined with any other document except where such other document is needed to satisfy the requirements at paragraph (c)(iv) of this section or at § 164.502(a)(5)(iii)(C), as applicable.

(c) Implementation specifications: Content requirements and other obligations—(1) Required elements. A valid attestation under this section must contain the following elements:

(i) A description of the information requested that identifies the information in a specific fashion, including one of the following:

(A) The name of any individual(s) whose protected health information is sought, if practicable.

(B) If including the name(s) of any individual(s) whose protected health information is sought is not practicable, a description of the class of individuals whose protected health information is sought.

(ii) The name or other specific identification of the person(s), or class of persons, who are requested to make the use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity is to make the requested use or disclosure.

(iv) A clear statement that the use or disclosure is not for a purpose prohibited under § 164.502(a)(5)(iii).

(v) A statement that a person may be subject to criminal penalties pursuant to 42 U.S.C. 1320d-6 if that person knowingly and in violation of HIPAA obtains individually identifiable health information relating to an individual or discloses individually identifiable health information to another person.

(vi) Signature of the person requesting the protected health information, which may be an electronic signature, and date. If the attestation is signed by a representative of the person requesting the information, a description of such representative's authority to act for the person must also be provided.

(2) Plain language requirement. The attestation must be written in plain language.

(d) Material misrepresentations. If, during the course of using or disclosing protected health information in reasonable reliance on a facially valid attestation, a covered entity or business associate discovers information reasonably showing that any representation made in the attestation was materially false, leading to a use or disclosure for a purpose prohibited under § 164.502(a)(5)(iii), the covered entity or business associate must cease such use or disclosure.

* * * * *45 CFR § 164.512

6. Amend § 164.512 by:

a. Revising the introductory text and the paragraph (c) paragraph heading;

b. Adding paragraph (c)(3); and

c. Revising paragraph (f)(1)(ii)(C) introductory text.

The revisions and addition read as follows:

45 CFR § 164.512

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

Except as provided by § 164.502(a)(5)(iii), a covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section and § 164.509. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given verbally.

* * * * *

(c) Standard: Disclosures about victims of abuse, neglect, or domestic violence—* * *

(3) Rule of construction. Nothing in this section shall be construed to permit disclosures prohibited by § 164.502(a)(5)(iii) when the sole basis of the report of abuse, neglect, or domestic violence is the provision or facilitation of reproductive health care.

* * * * *

(f) * * *

(1) * * *

(ii) * * *

(C) An administrative request for which response is required by law, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

* * * * *45 CFR § 164.520

7. Amend § 164.520 by:

a. Revising and republish paragraphs (a) and (b); and

b. Adding paragraph (d)(4).

The revisions and additions read as follows:

45 CFR § 164.520

§ 164.520 Notice of privacy practices for protected health information.

* * * * *

(a) Standard: Notice of privacy practices—(1) Right to notice. Except as provided by paragraph (a)(3) or (4) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.

(2) Notice requirements for covered entities creating or maintaining records subject to 42 U.S.C. 290dd-2. As provided in 42 CFR 2.22, an individual who is the subject of records protected under 42 CFR part 2 has a right to adequate notice of the uses and disclosures of such records, and of the individual's rights and the covered entity's legal duties with respect to such records.

(3) Exception for group health plans. (i) An individual enrolled in a group health plan has a right to notice:

(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or

(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.

(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in § 164.504(a)

or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:

(A) Maintain a notice under this section; and

(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.

(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in § 164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO *33065 offered by the plan, is not required to maintain or provide a notice under this section.

(4) Exception for inmates. An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.

(b) Implementation specifications: Content of notice—(1) Required elements. The covered entity, including any covered entity receiving or maintaining records subject to 42 U.S.C. 290dd-2, must provide a notice that is written in plain language and that contains the elements required by this paragraph.

(i) Header. The notice must contain the following statement as a header or otherwise prominently displayed:

“THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.”

(ii) Uses and disclosures. The notice must contain:

(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.

(B) A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written authorization.

(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, such as 42 CFR part 2, the description of such use or disclosure must reflect the more stringent law as defined in § 160.202 of this subchapter.

(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law, such as 42 CFR part 2.

(E) A description of the types of uses and disclosures that require an authorization under § 164.508(a)(2)-(a)(4), a statement that other uses and disclosures not described in the notice will be made only with the individual's written authorization, and a statement that the individual may revoke an authorization as provided by § 164.508(b)(5).

(F) A description, including at least one example, of the types of uses and disclosures prohibited under § 164.502(a)(5)(iii) in sufficient detail for an individual to understand the prohibition.

(G) A description, including at least one example, of the types of uses and disclosures for which an attestation is required under § 164.509.

(H) A statement adequate to put the individual on notice of the potential for information disclosed pursuant to this subpart to be subject to redisclosure by the recipient and no longer protected by this subpart

(iii) Separate statements for certain uses or disclosures. If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) or (B) of this section must include a separate statement informing the individual of such activities, as applicable:

(A) In accordance with § 164.514(f)(1), the covered entity may contact the individual to raise funds for the covered entity and the individual has a right to opt out of receiving such communications;

(B) In accordance with § 164.504(f), the group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan;

(C) If a covered entity that is a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of health plan, intends to use or disclose protected health information for underwriting purposes, a statement that the covered entity is prohibited from using or disclosing protected health information that is genetic information of an individual for such purposes;

(D) Substance use disorder treatment records received from programs subject to 42 CFR part 2, or testimony relaying the content of such records, shall not be used or disclosed in civil, criminal, administrative, or legislative proceedings against the individual unless based on written consent, or a court order after notice and an opportunity to be heard is provided to the individual or the holder of the record, as provided in 42 CFR part 2. A court order authorizing use or disclosure must be accompanied by a subpoena or other legal requirement compelling disclosure before the requested record is used or disclosed; or

(E) If a covered entity that creates or maintains records subject to 42 CFR part 2 intends to use or disclose such records for fundraising for the benefit of the covered entity, the individual must first be provided with a clear and conspicuous opportunity to elect not to receive any fundraising communications.

(iv) Individual rights. The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:

(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by § 164.522(a), including a statement that the covered entity is not required to agree to a requested restriction, except in case of a disclosure restricted under § 164.522(a)(1)(vi);

(B) The right to receive confidential communications of protected health information as provided by § 164.522(b), as applicable;

(C) The right to inspect and copy protected health information as provided by § 164.524;

(D) The right to amend protected health information as provided by § 164.526;

(E) The right to receive an accounting of disclosures of protected health information as provided by § 164.528; and

(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.

(v) Covered entity's duties. The notice must contain:

(A) A statement that the covered entity is required by law to maintain the privacy of protected health information, to provide individuals with notice of its legal duties and privacy practices, and to notify affected individuals following a breach of unsecured protected health information;

(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and

(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.

(vi) Complaints. The notice must contain a statement that individuals may complain to the covered entity and *33066 to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.

(vii) Contact. The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by § 164.530(a)(1)(ii).

(viii) Effective date. The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.

(2) Optional elements. (i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by § 164.512(j)(1)(i).

(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.

(3) Revisions to the notice. The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.

* * * * *

(d) * * *

* * * * *

(4) The permission in paragraph (d) of this section for covered entities that participate in an organized health care arrangement to issue a joint notice may not be construed to remove any obligations or duties of entities creating or maintaining records subject to 42 U.S.C. 290dd-2, or to remove any rights of patients who are the subjects of such records.

* * * * *45 CFR § 164.535

8. Add § 164.535 to read as follows:

45 CFR § 164.535

§ 164.535 Severability.

If any provision of the HIPAA Privacy Rule to Support Reproductive Health Care Privacy is held to be invalid or unenforceable facially, or as applied to any person, plaintiff, or circumstance, it shall be construed to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which case the provision shall

be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

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Footnotes

- 1 Subtitle F of title II of HIPAA (Pub. L. 104-191, 110 Stat. 1936 (Aug. 21, 1996)) added a new part C to title XI of the Social Security Act of 1935 (SSA), Public Law 74-271, 49 Stat. 620 (Aug. 14, 1935), (see sections 1171-1179 of the SSA (codified at [42 U.S.C. 1320d-1320d-8](#))), as well as promulgating section 264 of HIPAA (codified at [42 U.S.C. 1320d-2](#) note), which authorizes the Secretary to promulgate regulations with respect to the privacy of individually identifiable health information. The Privacy Rule has subsequently been amended pursuant to the Genetic Information Nondiscrimination Act of 2008 (GINA), title I, section 105, Public Law 110-233, 122 Stat. 881 (May 21, 2008) (codified at [42 U.S.C. 2000ff](#)), and the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, Public Law 111-5, 123 Stat. 226 (Feb. 17, 2009) (codified at [42 U.S.C. 1390w-4\(O\)\(2\)](#)).
- 2 45 CFR parts 160 and 164, subparts A and E. For a history of the Privacy Rule, see *infra* Section II.B., “Regulatory History.”
- 3 See also the HIPAA Security Rule, 45 CFR parts 160 and 164, subparts A and C; the HIPAA Breach Notification Rule, 45 CFR part 164, subpart D; and the HIPAA Enforcement Rule, 45 CFR part 160, subparts C, D, and E.
- 4 [45 CFR 160.103](#) (definition of “Protected health information”).
- 5 [42 U.S.C. 1320d](#). See also [45 CFR 160.103](#) (definition of “Individually identifiable health information”).
- 6 At times throughout this final rule, the Department uses the terms “health information” or “individuals’ health information” to refer generically to health information pertaining to an individual or individuals. In contrast, the Department’s use of the term “IIHI” refers to a category of health information defined in HIPAA, and “PHI” is used to refer specifically to a category of IIHI that is defined by and subject to the privacy and security standards promulgated in the HIPAA Rules.
- 7 See [45 CFR 164.502\(2\)](#) and (4).
- 8 See [45 CFR 164.512\(i\)](#) and [164.502\(a\)\(5\)\(ii\)](#).
- 9 See [45 CFR 164.501](#) and [164.508\(a\)\(2\)](#).
- 10 Section 1174(b)(1) of Public Law 104-191 (codified at [42 U.S.C. 1320d-3](#)).
- 11 597 U.S. 215 (2022).

- 12 See Melissa Suran, “Treating Cancer in Pregnant Patients After Roe v Wade Overturned,” JAMA (Sept. 29, 2022), <https://jamanetwork-com.hhsnih.idm.oclc.org/journals/jama/fullarticle/2797062?resultClick=1> and Rita Rubin, “How Abortion Bans Could Affect Care for Miscarriage and Infertility,” JAMA (June 28, 2022), <https://jamanetwork-com.hhsnih.idm.oclc.org/journals/jama/fullarticle/2793921?resultClick=1>.
- 13 See *infra* National Committee on Vital and Health Statistics (NCVHS) discussion, Section II.A.1., expressing concern for harm caused by disclosing identifiable health information for non-health care purposes.
- 14 See Whitney S. Rice et al. “ ‘Post-Roe’ Abortion Policy Context Heightens Imperative for Multilevel, Comprehensive, Integrated Health Education,” (Sept. 29, 2022), <https://journals.sagepub.com/doi/full/10.1177/10901981221125399> (“New ethical and legal complexities around patient counseling are emerging, particularly in states limiting or eliminating abortion access, due to more extreme abortion restrictions. Clinicians in such contexts may be forced to adhere to legal requirements of states which run counter to well-being and desires of patients, violating the medical principles of beneficence and respect for patient autonomy”).
- 15 [88 FR 23506 \(Apr. 17, 2023\)](#).
- 16 See [65 FR 67249 \(Nov. 11, 2000\)](#). See also Presidential Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships (Jan. 26, 2021), <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/26/memorandum-on-tribal-consultation-and-strengthening-nation-to-nation-relationships/> and Dep’t of Health and Human Servs., Tribal Consultation Policy, <https://www.hhs.gov/sites/default/files/iea/tribal/tribalconsultation/hhs-consultation-policy.pdf>. See also [88 FR 23506 \(Apr. 17, 2023\)](#) (notice of Tribal consultation). The Department consulted with representatives of Tribal Nations on May 17, 2023. During the consultation, the representatives raised issues of health inequities and privacy of health information, specifically among American Indians and Alaskan Natives after Dobbs.
- 17 Letter from U.S. Senator Tammy Baldwin et al. to HHS Sec’y Xavier Becerra (Mar. 7, 2023) (addressing HIPAA privacy regulations and Dobbs v. Jackson Women’s Health Organization). Letter from U.S. Senator Patty Murray et al. to HHS Sec’y Xavier Becerra (Sept. 13, 2022) (addressing HIPAA privacy regulations and Dobbs v. Jackson Women’s Health Organization). Letter from U.S. Representative Earl Blumenauer et al. to HHS Sec’y Xavier Becerra (Aug. 30, 2022) (addressing HIPAA privacy regulations and Dobbs v. Jackson Women’s Health Organization). Letter from U.S. Senator Michael F. Bennet et al. to HHS Sec’y Xavier Becerra (July 1, 2022) (addressing HIPAA privacy regulations and Dobbs v. Jackson Women’s Health Organization).
- 18 See [88 FR 23506, 23510 \(Apr. 17, 2023\)](#).
- 19 See *id.*
- 20 [45 CFR 160.104\(a\)](#).
- 21 [45 CFR 160.104\(c\)\(2\)](#).
- 22 [87 FR 74216 \(Dec. 2, 2022\)](#).
- 23 Public Law 116-136, 134 Stat. 281 (Mar. 27, 2020).
- 24 [89 FR 12472 \(Feb. 16, 2024\)](#).
- 25 *Id.* at 12482, 12528, and 12530.
- 26 *Id.* at 12482, 12528, and 12530.
- 27 [89 FR 12472 \(Feb. 16, 2024\)](#).

- 28 Public Law 104-191, 110 Stat. 1936 (Aug. 21, 1996).
- 29 See H.R. Rep. No. 104-496, at 66-67 (1996).
- 30 [42 U.S.C. 1320d](#) note (Statutory Notes and Related Subsidiaries: Purpose). Subtitle F also amended related provisions of the SSA.
- 31 See section 262 of Public Law 104-191, adding section 1172 to the SSA (codified at [42 U.S.C. 1320d-1](#)). See also section 13404 of the American Recovery and Reinvestment Act of 2009, Public Law 111-5, 123 Stat. 115 (Feb. 17, 2009) (codified at [42 U.S.C. 17934](#)) (applying privacy provisions and penalties to business associates of covered entities).
- 32 [42 U.S.C. 1320d2\(a\)\(1\)](#).
- 33 [42 U.S.C. 1320d-2\(b\)\(1\)](#).
- 34 [42 U.S.C. 1320d-2\(a\)](#), (c), and (f).
- 35 [42 U.S.C. 1320d-2\(d\)](#).
- 36 [42 U.S.C. 1320d-2\(e\)](#).
- 37 On a resolution waiving points of order against the Conference Report to H.R. 3103, members debated an “erosion of privacy” balanced against the administrative simplification provisions. Thus, from HIPAA's inception, privacy has been a central concern to be addressed as legislative changes eased disclosures of PHI. See 142 Cong. Rec. H9777 and H9780; see also H.R. Rep. No. 104-736, at 177 and 264 (1996); 142 Cong. Rec. H9780 (daily ed. Aug. 1, 1996) (statement of Rep. Sawyer); 142 Cong. Rec. H9792 (daily ed. Aug. 1, 1996) (statement of Rep. McDermott); and 142 Cong. Rec. S9515-16 (daily ed. Aug. 2, 1996) (statement of Sen. Simon).
- 38 [88 FR 23506, 23511 \(Apr. 17, 2023\)](#).
- 39 See statement of Rep. Sawyer, *supra* note 37. See also statement of Sen. Simon, *supra* note 37.
- 40 Statement of Rep. Sawyer, *supra* note 37.
- 41 See H.R. Rep. No. 104-496 Part 1, at 99-100 (Mar. 25, 1996).
- 42 [42 U.S.C. 1320d-2](#) note.
- 43 *Id.*
- 44 *Id.*
- 45 [42 U.S.C. 1320d-7](#).
- 46 [65 FR 82580](#) (the exception applies under section 1178(a)(2)(B) of the SSA and section 264(c)(2) of HIPAA).
- 47 NCVHS serves as the Secretary's statutory public advisory body for health data, statistics, privacy, and national health information policy and HIPAA. NCVHS also advises the Secretary, “reports regularly to Congress on HIPAA implementation, and serves as a forum for interaction between HHS and interested private sector groups on a range of health data issues.” Nat'l Comm. On Vital and Health Statistics, “About NCVHS,” <https://ncvhs.hhs.gov/>; see also “NCVHS 60th Anniversary Symposium and History,” U.S. Dep't of Health and Human Servs., at 28-29 (Feb. 2011), https://ncvhs.hhs.gov/wp-content/uploads/2014/05/60_years_of_difference.pdf.
- 48 See section 264(a) and (d) of Public Law 104-191 (codified at [42 U.S.C. 1320d-2](#) note).

- 49 Letter from NCVHS Chair Don E. Detmer to HHS Sec'y Donna E. Shalala (June 27, 1997) (forwarding NCVHS recommendations), <https://ncvhs.hhs.gov/rrp/june-27-1997-letter-to-the-secretary-with-recommendations-on-health-privacy-and-confidentiality/>.
- 50 Id. at Principal Findings and Recommendations.
- 51 Id.
- 52 Id. at Third-Party Disclosures.
- 53 [88 FR 23506, 23513 \(Apr. 17, 2023\)](#).
- 54 See section 1174(b)(1) of Public Law 104-191 (codified at [42 U.S.C. 1320d-3](#)).
- 55 Section 1102 of the SSA (codified at [42 U.S.C. 1302](#)).
- 56 Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009, Public Law 111-5, 123 Stat. 115 (Feb. 17, 2009) (codified at [42 U.S.C. 201](#) note).
- 57 C. Stephen Redhead, Cong. Rsch. Serv., R40161, “The Health Information Technology for Economic and Clinical Health (HITECH) Act,” (2009), <https://crsreports.congress.gov/product/pdf/R/R40161/9> (“[Health IT], which generally refers to the use of computer applications in medical practice, is widely viewed as a necessary and vital component of health care reform.”).
- 58 H.R. Rep. No. 111-7, at 74 (2009), accompanying H.R. 629, 111th Cong.
- 59 H.R. 629, Energy and Commerce Recovery and Reinvestment Act of 2009, introduced in the House on January 22, 2009, contained nearly identical provisions to subtitle D of the HITECH Act.
- 60 Congress enacted the American Recovery and Reinvestment Act of 2009, which included the HITECH Act, on February 17, 2009. While it was the House version of the bill, H.R. 1, that was enacted, the Senate version, S. 336, contained nearly identical provisions to subtitle D of the HITECH Act.
- 61 S. Rep. No. 111-3 accompanying S. 336, 111th Cong., at 59 (2009).
- 62 [78 FR 5566 \(Jan. 25, 2013\)](#).
- 63 Subtitle D of title XIII of the HITECH Act (codified at [42 U.S.C. 17921](#), [42 U.S.C. 17931-17941](#), and [42 U.S.C. 17951-17953](#)).
- 64 [78 FR 5566, 5568 \(Jan. 25, 2013\)](#).
- 65 Section 3009(a)(1)(B) of the PHSA, as added by section 13101 of the HITECH Act (codified at [42 U.S.C. 300jj-19\(a\)\(1\)](#)).
- 66 Section 13421(b) of the HITECH Act (codified at [42 U.S.C. 17951](#)).
- 67 Section 3009(a)(1)(A) of the PHSA, as added by section 13101 of the HITECH Act (codified at [42 U.S.C. 300jj-19\(a\)\(1\)](#)).
- 68 See U.S. Dep't of Health and Hum. Servs., Off. of the Sec'y, [Off. for Civil Rights; Statement of Delegation of Authority](#), [65 FR 82381 \(Dec. 28, 2000\)](#); U.S. Dep't of Health and Hum. Servs., Off. of the Sec'y, [Off. for Civil Rights; Delegation of Authority](#), [74 FR 38630 \(Aug. 4, 2009\)](#); U.S. Dep't of Health and Hum. Servs., Off. of the Sec'y, [Statement of Organization, Functions and Delegations of Authority](#), [81 FR 95622 \(Dec. 28, 2016\)](#).

- 69 See 78 FR 5566 (Jan. 25, 2013); 79 FR 7290 (Feb. 6, 2014); 81 FR 382 (Jan. 6, 2016).
- 70 See U.S. Dep't of Health and Hum. Servs., Off. of the Assistant Sec'y for Plan. and Evaluation, "Recommendations of the Secretary of Health and Human Services, pursuant to section 264 of the Health Insurance Portability and Accountability Act of 1996," Section I.A. (Sept. 1997), <https://aspe.hhs.gov/reports/confidentiality-individually-identifiable-health-information>.
- 71 64 FR 59918 (Nov. 3, 1999).
- 72 65 FR 82462 (Dec. 28, 2000).
- 73 *Id.*
- 74 See Executive Order 13181 (Dec. 20, 2000), 65 FR 81321.
- 75 See 65 FR 82462, 82471 (Dec. 28, 2000).
- 76 See *id.* at 82472.
- 77 See *id.*
- 78 65 FR 82462 (Dec. 28, 2000).
- 79 45 CFR 164.506 was originally titled "Consent for uses or disclosures to carry out treatment, payment, or health care operations."
- 80 45 CFR 164.508.
- 81 45 CFR 164.510.
- 82 45 CFR 164.512.
- 83 See 64 FR 59918, 59955 (Nov. 3, 1999).
- 84 See 45 CFR 164.520, 164.522, 164.524, 164.526, and 164.528.
- 85 See 65 FR 82462, 82800 (Dec. 28, 2000).
- 86 See 67 FR 53182 (Aug. 14, 2002).
- 87 78 FR 5566 (Jan. 25, 2013).
- 88 81 FR 382 (Jan. 6, 2016).
- 89 66 FR 12738 (Feb. 28, 2001).
- 90 67 FR 53182, 53183 (Aug. 14, 2002).
- 91 67 FR 14775 (Mar. 27, 2002).
- 92 67 FR 53182 (Aug. 14, 2002). See the final rule for changes in the entirety. The 2002 Privacy Rule was issued before the compliance date for the 2000 Privacy Rule. Thus, covered entities never implemented the 2000 Privacy Rule. Instead, they implemented the 2000 Privacy Rule as modified by the 2002 Privacy Rule.
- 93 See 67 FR 53182 (Aug. 14, 2002).

- 94 [75 FR 40868](#) (July 14, 2010).
- 95 [78 FR 5566](#) (Jan. 25, 2013). In addition to finalizing requirements of the HITECH Act that were proposed in the 2010 NPRM, the Department adopted modifications to the Enforcement Rule not previously adopted in an earlier interim final rule, [74 FR 56123](#) (Oct. 30, 2009), and to the Breach Notification Rule not previously adopted in an interim final rule, [74 FR 42739](#) (Aug. 24, 2009). The Department also finalized previously proposed Privacy Rule modifications as required by GINA, [74 FR 51698](#) (Oct. 7, 2009).
- 96 See [78 FR 5566](#) (Jan. 25, 2013) (explaining that the Department was using its general authority under HIPAA to make a number of changes to the Privacy Rule that were intended to increase workability and flexibility, decrease burden, and better harmonize the requirements with those under other Departmental regulations). The Department's general authority to modify the Privacy Rule is codified in HIPAA section 264(c), and OCR conducts rulemaking under HIPAA based on authority granted by the Secretary.
- 97 See [75 FR 40868](#), [40871](#) (July 14, 2010).
- 98 [75 FR 40868](#), [40871](#) (July 14, 2010).
- 99 See [78 FR 5566](#), [5611](#) (Jan. 25, 2013).
- 100 See [id.](#) at [5612](#).
- 101 Id. at [5616-17](#). See also [45 CFR 164.512\(b\)\(1\)](#).
- 102 [78 FR 5566](#), [5614](#) (Jan. 25, 2013). See also [45 CFR 164.502\(f\)](#) and the definition of “Protected health information” at [45 CFR 160.103](#), excluding IIHI regarding a person who has been deceased for more than 50 years.
- 103 In addition to the rulemakings discussed here, the Department has modified the Privacy Rule for workability purposes and in response to changes in circumstances on two other occasions, and it issued another notice of proposed rulemaking in 2021 for the same reasons. See [79 FR 7289](#) (Feb. 6, 2014), [81 FR 382](#) (Jan. 6, 2016), and [86 FR 6446](#) (Jan. 21, 2021).
- 104 See Letter from NCVHS Chair Simon P. Cohn to HHS Sec'y Michael O. Leavitt (June 22, 2006), <https://ncvhs.hhs.gov/rrp/june-22-2006-letter-to-the-secretary-recommendations-regarding-privacy-and-confidentiality-in-the-nationwide-health-information-network/>; Letter from NCVHS Chair Simon P. Cohn to HHS Sec'y Michael O. Leavitt (Feb. 20, 2008) (listing categories of health information that are commonly considered to contain sensitive information), <https://ncvhs.hhs.gov/wp-content/uploads/2014/05/080220lt.pdf>; Letter from NCVHS Chair Justine M. Carr to HHS Sec'y Kathleen Sebelius (Nov. 10, 2010) (forwarding NCVHS recommendations), <https://ncvhs.hhs.gov/wp-content/uploads/2014/05/101110lt.pdf>.
- 105 [88 FR 23506](#).
- 106 See Meeting of NCVHS (June 14, 2023), <https://ncvhs.hhs.gov/meetings/full-committee-meeting-13/>.
- 107 See Meeting of NCVHS, Briefing on Legislative Developments in Data Privacy (July 21, 2022), <https://ncvhs.hhs.gov/meetings/full-committee-meeting-11/>.
- 108 See Meeting of NCVHS, Briefing by Cason Schmit (Dec. 7, 2022), <https://ncvhs.hhs.gov/meetings/full-committee-meeting-12/>.
- 109 Letter from NCVHS Chair Jacki Monson to HHS Sec'y Xavier Becerra (June 14, 2023) (forwarding NCVHS recommendations), <https://ncvhs.hhs.gov/wp-content/uploads/2023/06/NCVHS-Comments-on-HIPAA-Reproduction-Health-NPRM-Final-508.pdf>.

- 110 See Jennifer Richmond et al., “Development and Validation of the Trust in My Doctor, Trust in Doctors in General, and Trust in the Health Care Team Scales,” 298 *Social Science & Medicine* 114827 (2022), <https://www.sciencedirect.com/science/article/abs/pii/S0277953622001332?via%3Dihub>; see also Fallon E. Chipidza et al., “Impact of the Doctor-Patient Relationship,” *The Primary Care Companion for CNS Disorders* (Oct. 2015), <https://www.psychiatrist.com/pcc/delivery/patient-physician-communication/impact-doctor-patient-relationship/>. See Testimony (transcribed) of William G. Plested, III, M.D., Member, Board of Trustees, American Medical Association, Hearing on Confidentiality of Patient Medical Records before House of Representatives Committee on Ways and Means, Subcommittee on Health (Feb. 17, 2000), <https://www.govinfo.gov/content/pkg/CHRG-106hhrg66897/html/CHRG-106hhrg66897.htm>. (“Trust is the foundation of the patient/physician relationship.”)
- 111 See Am. Med. Ass’n, “Patient Perspectives Around Data Privacy,” (2022), <https://www.ama-assn.org/system/files/ama-patient-data-privacy-survey-results.pdf>.
- 112 See John C. Moskop et al., “From Hippocrates to HIPAA: Privacy and Confidentiality in Emergency Medicine—Part I: Conceptual, Moral, and Legal Foundations,” 45 *Ann Emerg. Med.* 1 (Jan. 2005) (quoting the Oath of Hippocrates, “What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself [. . .].”), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7132445/#bib1>.
- 113 See 64 FR 59918, 60006 (Nov. 3, 1999) (In the 1999 Privacy Rule NPRM, the Department discussed confidentiality as an important component of trust between individuals and health care providers and cited a 1994 consumer privacy survey that indicated that a lack of privacy may deter patients from obtaining preventive care and treatment.). See *id.* at 60019.
- 114 See 64 FR 59918, 60006 (Nov. 3, 1999).
- 115 See “Patient Perspectives Around Data Privacy,” *supra* note 111.
- 116 *Id.* at 2.
- 117 See Testimony (transcribed) of Peter R. Orszag, Director, Congressional Budget Office, Hearing on Comparative Clinical Effectiveness before House of Representatives Committee on Ways and Means, Subcommittee on Health, 2007 WL 1686358 (June 12, 2007) (“because federal health insurance programs play a large role in financing medical care and represent a significant expenditure, the federal government itself has an interest in evaluations of the effectiveness of different health care approaches”); Statement of Sen. Durenberger introducing S.1836, American Health Quality Act of 1991 and reading bill text, 137 Cong. Rec. S26720 (Oct. 17, 1991) (“[T]he Federal Government has a demonstrated interest in assessing the quality of care, access to care, and the costs of care through the evaluative activities of several Federal agencies.”).
- 118 See 65 FR 82462, 82463 (Dec. 28, 2000).
- 119 See, e.g., Brooke Rockwern et al., Medical Informatics Committee and Ethics, Professionalism and Human Rights Committee of the American College of Physicians, “Health Information Privacy, Protection, and Use in the Expanding Digital Health Ecosystem: A Position Paper of the American College of Physicians,” 174 *Ann Intern Med.* 994 (Jul. 2021) (discussing the need for trust in the health care system as necessary to mitigate a global pandemic); Johanna Birkh[auml]uer et. al, “Trust in the Health Care Professional and Health Outcome: A Meta-Analysis,” 12 *PLoS One* e0170988 (Feb. 7, 2017). See also Eric Boodman, “In a doctor’s suspicion after a miscarriage, a glimpse of expanding medical mistrust,” *STAT News* (June 29, 2022), <https://www.statnews.com/2022/06/29/doctor-suspicion-after-miscarriage-glimpse-of-expanding-medical-mistrust/> (Sarah Prager, professor of obstetrics and gynecology at the University of Washington, stating that it is a bad precedent if clinical spaces become unsafe for patients because, “[a health care provider’s] ability to take care of patients relies on trust, and that will be impossible moving forward.”).

- 120 See “Development and Validation of the Trust in My Doctor, Trust in Doctors in General, and Trust in the Health Care Team Scales,” *supra* note 110; Bradley E. Iott et al., “Trust and Privacy: How Patient Trust in Providers is Related to Privacy Behaviors and Attitudes,” 2019 AMIA Annu Symp Proc 487 (Mar. 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7153104/>; Pamela Sankar et al., “Patient Perspectives of Medical Confidentiality: a Review of the Literature,” 18 J. of Gen. Internal Med. 659 (Aug. 2003), <https://pubmed.ncbi.nlm.nih.gov/12911650/>.
- 121 See 65 FR 82462, 82468 (Dec. 28, 2000).
- 122 See Letter from NCVHS Chair Simon P. Cohn, *supra* note 104, at 2 (2006) (with forwarded NCVHS recommendations, “Individual trust in the privacy and confidentiality of their personal health information also promotes public health, because individuals with potentially contagious or communicable diseases are not inhibited from seeking treatment.”).
- 123 See Texas Dep’t of State Health Servs., “Texas Maternal Mortality and Morbidity Review Committee and Department of State Health Services Joint Biennial Report 2022,” at 41 (Dec. 2022) <https://www.dshs.texas.gov/sites/default/files/legislative/2022-Reports/2022-MMMRC-DSHS-Joint-Biennial-Report.pdf>; Lynn M. Paltrow et al., “Arrests of and forced interventions on pregnant women in the United States, 1973-2005: implications for women’s legal status and public health,” 38 J. Health Pol. Pol’y Law 299 (2013) (finding that hospital staff are most likely to report pregnant low-income and patients of color, especially Black women, to the authorities.); Terri-ann Monique Thompson et al., “Racism Runs Through It: Examining the Sexual and Reproductive Health Experience of Black Women in the South,” 41 Health Affairs 195 (Feb. 2022) (discussing how individual racism affects reproductive health care use by undermining the patient-doctor relationship), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01422>; Joli Hunt, “Maternal Mortality among Black Women in the United States,” Ballard Brief (July 2021), <https://ballardbrief.byu.edu/issue-briefs/maternal-mortality-among-black-women-in-the-united-states/> (discussing the disproportionately high rate of Black maternal mortality and morbidity); Austin Frakt, “Bad Medicine: The Harm that Comes from Racism,” The New York Times (July 8, 2020), <https://www.nytimes.com/2020/01/13/upshot/bad-medicine-the-harm-that-comes-from-racism.html>.
- 124 42 U.S.C. 1320d note and 1320d-2 note.
- 125 See 67 FR 53182, 53216 (Aug. 14, 2002).
- 126 *Id.* at 53226.
- 127 65 FR 82462, 82464 (Dec. 28, 2000).
- 128 See 78 FR 5566, 5616 (Jan. 25, 2013).
- 129 81 FR 382 (Jan. 6, 2016); see, e.g., 78 FR 4297 (Jan. 22, 2013) and 78 FR 4295 (Jan. 22, 2013); see also Colleen Curtis, “President Obama Announces New Measures to Prevent Gun Violence,” The White House President Barack Obama (Jan. 16, 2013), <https://obamawhitehouse.archives.gov/blog/2013/01/16/president-obama-announces-new-measures-prevent-gun-violence>.
- 130 This PHI includes limited demographic and certain other information needed for the purposes of reporting to NICS. 45 CFR 164.512(k)(7)(iii)(A). In preamble, the Department explained that generally the information described at 45 CFR 164.512(k)(7)(iii)(A) would be limited to the data elements required to create a NICS record and certain other elements to the extent that they are necessary to exclude false matches: Social Security number, State of residence, height, weight, place of birth, eye color, hair color, and race. 81 FR 382, 390 (Jan. 6, 2016).
- 131 81 FR 382, 386-388 (Jan. 6, 2016).
- 132 *Id.* The Department addressed concerns about the possible chilling effect on individuals seeking health care by explaining that (1) the permission is limited to only those covered entities that order the involuntary commitments or make the other adjudications that cause individuals to be subject to the Federal mental health prohibitor, or that serve as repositories of

such information for NICS reporting purposes; (2) the specified regulated entities are permitted to disclose NICS data only to designated repositories or the NICS; (3) the information that may be disclosed is limited to certain demographic or other information that is necessary for NICS reporting; and (4) the rulemaking did not expand the permission to encompass State law prohibitor information.

- 133 Letter from NCVHS Chair Don E. Detmer to HHS Sec'y Donna E. Shalala (June 27, 1997) (forwarding NCVHS recommendations), <https://ncvhs.hhs.gov/rrp/june-27-1997-letter-to-the-secretary-with-recommendations-on-health-privacy-and-confidentiality/>.
- 134 42 U.S.C. 1320d-2 note.
- 135 See 45 CFR 164.501 (definition of “Psychotherapy notes”).
- 136 See 64 FR 59918, 59941 (Nov. 3, 1999).
- 137 See *id.*
- 138 45 CFR 164.508(a)(2).
- 139 Council on Ethical and Judicial Affairs, “Ethics, Amendment to Opinion 4.2.7, Abortion H-140.823,” Am. Med. Ass'n (2022), <https://policysearch.ama-assn.org/policyfinder/detail/4.2.7Abortion?uri=@AMADoc@HOD.xml-H-140.823.xml>.
- 140 See Letter from NCVHS Chair Simon P. Cohn (2006), *supra* note 104.
- 141 See Letter from NCVHS Chair Simon P. Cohn (2006), *supra* note 104; Letter from NCVHS Chair Simon P. Cohn (2008), *supra* note 104; Letter from NCVHS Chair Justine M. Carr (2010), *supra* note 104.
- 142 See Letter from NCVHS Chair Justine M. Carr (2010), *supra* note 104.
- 143 See *LePage v. Center for Reproductive Medicine*, SC-2022-0515 (Feb. 16, 2024).
- 144 410 U.S. 113 (1973).
- 145 505 U.S. 833 (1992).
- 146 *Dobbs*, 597 U.S. 299-302.
- 147 See, e.g., Carmel Shachar et al., “Informational Privacy After *Dobbs*,” 75 Ala. L. Rev. 1 (2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4570500 and Andrzej Kulczycki, “*Dobbs*: Navigating the New Quagmire and Its Impacts on Abortion and Reproductive Health Care,” *Health Education & Behavior* (2022), <https://doi.org/10.1177/10901981221125430>.
- 148 See, e.g., Kayte Spector-Bagdady & Michelle M. Mello, “Protecting the Privacy of Reproductive Health Information After the Fall of *Roe v. Wade*,” 3 JAMA Network e222656 (June 30, 2022), <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2794032>; Lisa G. Gill, “What does the overturn of *Roe v. Wade* mean for you?,” *Consumer Reports* (June 24, 2022), <https://www.consumerreports.org/health-privacy/what-does-the-overturn-of-roe-v-wade-mean-for-you-a1957506408/>.
- 149 45 CFR 164.502(a)(1).
- 150 45 CFR 164.512(a).

- 151 See Laura J. Faherty et al. “Consensus Guidelines and State Policies: The Gap Between Principle and Practice at the Intersection of Substance Use and Pregnancy,” *American Journal of Obstetrics & Gynecology Maternal-Fetal Medicine* (Aug. 2020) (discussing a concern raised by multiple organizations that pregnant women will hesitate to seek prenatal care and addiction treatment during pregnancy because their concerns that disclosing substance use to health care providers will increase the likelihood that they will face legal penalties); see also “Informational Privacy After Dobbs,” *supra* note 147.
- 152 See, e.g., Yvonne Lindgren et al., “Reclaiming Tort Law to Protect Reproductive Rights,” 75 *Alabama L. Rev.* 355 (2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4435834.
- 153 See section 3001(c) of the PHSA, as amended by section 4003(b) of the 21st Century Cures Act, Public Law 114-255, 130 Stat. 1165 (codified at 42 U.S.C. 300jj-11(c)). For more information, see Office of the Nat'l Coordinator for Health Info. Tech., “Trusted Exchange Framework and Common Agreement (TEFCA),” <https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca>; See also 89 FR 8758 (Feb. 8, 2024); “CMS Interoperability and Prior Authorization Final Rule CMS-0057-F,” Centers for Medicare & Medicaid (Jan. 17, 2024), <https://www.cms.gov/newsroom/fact-sheets/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f>.
- 154 See Eric Boodman, “In a doctor's suspicion after a miscarriage, a glimpse of expanding medical mistrust,” *STAT News* (June 29, 2022), <https://www.statnews.com/2022/06/29/doctor-suspicion-after-miscarriage-glimpse-of-expanding-medical-mistrust/>
 #:#:text=Inadoctor'ssuspicionafter,glimpseofexpandingmedicalmistrust&text=Theideathatshe,usedcontraceptivesandtrustedthem.
- 155 See also Melissa Suran, “As Laws Restricting Health Care Surge, Some US Physicians Choose Between Fight or Flight,” *JAMA*, 329(22):1899-1903 (May 17, 2023) (discussing a maternal-fetal medicine specialist who stated that she moved to another state because of legislation that restricts evidence-based health care and prevents her from fulfilling her ethical obligation to protect her patients' health.), <https://pubmed.ncbi.nlm.nih.gov/37195699/>.
- 156 See Off. for Civil Rights, “HHS Office for Civil Rights Resolves Complaints with CVS and Walgreens to Ensure Timely Access to Medications for Women and Support Persons with Disabilities,” U.S. Dep't of Health and Human Servs. (June 16, 2023), <https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/agreements/cvs-walgreens/index.html>. See also Kathryn Starzyk et al., “More than half of patients with a rheumatic disease or immunologic condition undergoing methotrexate treatment reside in states in which the overturning of *Roe v. Wade* can jeopardize access to medications with abortifacient potential,” 75 *Arthritis Rheumatol* 328 (Feb. 2023); see also Celine Castronuovo, “Many Female Arthritis Drug Users Face Restrictions After Dobbs,” *Bloomberg Law* (Nov. 14, 2022) (noting that 16 out of 524 patients responding to a survey indicated that they've had trouble getting methotrexate, their arthritis medication, since the Dobbs decision.) <https://news.bloomberglaw.com/health-law-and-business/many-female-arthritis-drug-users-face-restrictions-after-dobbs>; Interview with Donald Miller, PharmD, “Methotrexate access becomes challenging for some patients following Supreme Court decision on abortion,” *Pharmacy Times* (July 20, 2022), <https://www.pharmacytimes.com/view/methotrexate-access-becomes-challenging-for-patients-following-supreme-court-decision-on-abortion>; Jamie Ducharme, “Abortion restrictions may be making it harder for patients to get a cancer and arthritis drug,” *Time* (July 6, 2022), <https://time.com/6194179/abortion-restrictions-methotrexate-cancer-arthritis/>; Katie Shepherd & Frances Stead Sellers, “Abortion bans complicate access to drugs for cancer, arthritis, even ulcers,” *The Washington Post* (Aug. 8, 2022), <https://www.washingtonpost.com/health/2022/08/08/abortion-bans-methotrexate-mifepristone-rheumatoid-arthritis/>.
- 157 See Michelle Oberman & Lisa Soleymani Lehmann, “Doctors' duty to provide abortion information,” *J. of Law and Biosciences*. (Sept. 1, 2023) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10474560/>; Whitney Arey et al., “Abortion Access and Medically Complex Pregnancies Before and After Texas Senate Bill 8,” 141 *Obstet Gynecol.* 995 (May 1, 2023) (concluding that “Abortion restrictions limit shared decision making, compromise patient care, and

put pregnant people's health at risk.”); “1 Year Without Roe,” Center for American Progress (Jun. 23, 2023) (where a physician detailed her fear about speaking freely with her patients after Dobbs “worried a vigilante posing as a new patient would attempt to bait her into talking about abortion and attempt to sue her, and she sometimes skirts the topic of abortion when speaking with patients about their health care options.”)

- 158 See Christine Dehlendorf et al., “Disparities in Abortion Rates: A Public Health Approach,” *Am. J. of Pub. Health* (Oct. 2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3780732/>. See also Kiara Alfonseca, “Why Abortion Restrictions Disproportionately Impact People of Color,” *ABC News* (June 24, 2022), <https://abcnews.go.com/Health/abortion-restrictions-disproportionately-impact-people-color/story?id=84467809>; Dulce Gonzalez et al., Robert Wood Johnson Foundation, “Perceptions of Discrimination and Unfair Judgment While Seeking Health Care” (Mar. 31, 2021), <https://www.rwjf.org/en/insights/our-research/2021/03/perceptions-of-discrimination-and-unfair-judgment-while-seeking-health-care.html>; Susan A. Cohen, “Abortion and Women of Color: The Bigger Picture,” 11 *Guttmacher Pol’y Rev.* (Aug. 6, 2008), <https://www.guttmacher.org/gpr/2008/08/abortion-and-women-color-bigger-picture>; “The Disproportionate Harm of Abortion Bans: Spotlight on Dobbs v. Jackson Women's Health,” Center for Reproductive Rights (Nov. 29, 2021), <https://reproductiverights.org/supreme-court-case-mississippi-abortion-ban-disproportionate-harm/> (“Abuses such as forced sterilization of Black, Indigenous, and other people of color and individuals with disabilities specifically exacerbate medical mistrust within reproductive healthcare.”).
- 159 See Brief of Amici Curiae for Organizations Dedicated to the Fight for Reproductive Justice—Mississippi in Action, et al. at *35-36, *Dobbs*, 597 U.S. 215 (discussing the likelihood that individuals, particularly those from marginalized communities who terminate their pregnancies and anyone who assists them may be disproportionately likely to face criminal investigation or arrest, given the rates of incarceration of persons from such communities.); see also Elizabeth Yuko, “Women of Color Will Face More Criminalized Pregnancies in Post-‘Roe’ America,” *Rolling Stone* (Jul. 7, 2020) (“Historically, we’ve seen the criminalization of people of color, young people, and people with lower incomes who’ve had miscarriages and other types of pregnancy losses that the state deemed were their fault [. . .] These groups are the most likely to be reported to law enforcement and investigated”); see also Sentencing Project, *State-by-State Data*, <https://www.sentencingproject.org/research/us-criminal-justice-data/> (last visited Feb. 16, 2024) (U.S. Total: Imprisonment rate per 100,000 residents—355; Black/White disparity—4.8:1; Latinx/White disparity—1.3:1); *Racial Disparities in Incarceration*, Vera Institute of Justice (Aug. 21, 2023), <https://trends.vera.org/> (Prison population rate per 100,000 residents ages 15 to 64. U.S. total incarceration rate 2021 Q2—298, Asian American/Pacific Islander incarceration rate 2021 Q2—100, Black/African American incarceration rate 2021 Q2—1,310, Latinx incarceration rate 2021 Q2—671, Native American incarceration rate 2021 Q2—1,021, White incarceration rate 2021 Q2—281).
- 160 See Columbia Law Sch. Hum. Rts. Inst. & and Ne. Univ. Sch. of Law Program on Hum. Rts. and the Glob. Econ., “Equal Access to Justice: Ensuring Meaningful Access to Counsel in Civil Cases, Including Immigration Proceedings” (July 2014), https://hri.law.columbia.edu/sites/default/files/publications/equal_access_to_justice_-_cerd_shadow_report.pdf. See also Lauren Hoffman et al., Ctr. For Am. Progress, “Report: State Abortion Bans Will Harm Women and Families’ Economic Security Across the US” (Aug. 25, 2022), <https://www.americanprogress.org/article/state-abortion-bans-will-harm-women-and-families-economic-security-across-the-us/>.
- 161 See Myasar Ihmud, “Lost in Translation: Language Barriers to Accessing Justice in the American Court System,” *UIC Law Review* (2023) (discussing “access to justice for [limited English proficient (LEP)] individuals is hindered because they are unable to communicate with the court or understand the proceedings. Case law shows that, when unable to communicate with the court, LEP litigants are unable to defend themselves appropriately in criminal or immigration hearings, protect their homes, or keep custody of their children.”), <https://repository.law.uic.edu/cgi/viewcontent.cgi?article=2908&context=lawreview>; see also “Language Access & Cultural Sensitivity,” Legal Services Corporation (last visited Feb. 21, 2024) (describing how legal aid organizations should plan for providing meaningful access to language services. As of 2013, “close to 25 million people, about 8 percent of the population, has limited English proficiency.”), <https://www.lsc.gov/i-am-grantee/model-practices-innovations/language-access-cultural-sensitivity>.

- 162 See, e.g., Gautam Gulati et al., “The experience of law enforcement officers interfacing with suspects who have an intellectual disability—A systematic review,” *International Journal of Law and Psychiatry* (Sept.-Oct. 2020) (“It is not uncommon for people with [intellectual disability] to be suspects or accused persons when interfacing with Law Enforcement Officers (LEOs) and therefore face arrest, interview and/or custody.”), <https://www.sciencedirect.com/science/article/pii/S016025272030073X>.
- 163 See Leslie Read et al., The Deloitte Ctr. for Health Solutions, “Rebuilding Trust in Health Care: What Do Consumers Want—and Need—Organizations to Do?,” at 3 (Aug. 5, 2021) (With focus groups of 525 individuals in the United States who identify as Black, Hispanic, Asian, or Native American, “[f]ifty-five percent reported a negative experience where they lost trust in a health care provider.”), <https://www2.deloitte.com/us/en/insights/industry/health-care/trust-in-health-care-system.html>; Liz Hamel et al., Kaiser Family Foundation, “The Undeclared Survey on Race and Health,” at 23 (Oct. 2020) (Percent who say they can trust the health care system to do what is right for them or their community almost all of the time or most of the time: Black adults: 44%; Hispanic adults: 50%; White adults: 55%), <https://files.kff.org/attachment/Report-Race-Health-and-COVID-19-The-Views-and-Experiences-of-Black-Americans.pdf>; U.S. Dep’t of Health and Hum. Servs., Assistant Sec’y for Pol. & Eval., Off. of Health Pol., “Issue Brief: Health Insurance Coverage and Access to Care for LGBTQ+ Individuals: Current Trends and Key Challenges,” at 9 (June 2021) (A 2021 survey found that 18 percent of LGBTQ+ individuals reported avoiding going to a doctor or seeking health care out of concern that they would face discrimination or poor treatment because of their sexual orientation or gender identity.), <https://aspe.hhs.gov/sites/default/files/2021-07/lgbt-health-ib.pdf>; Abigail A. Sewell, “Disaggregating Ethnoracial Disparities in Physician Trust,” *Soc. Science Rsch.* (Nov. 2015), <https://pubmed.ncbi.nlm.nih.gov/26463531/>; Irena Stepanikova et al., “Patients’ Race, Ethnicity, Language, and Trust in a Physician,” *J. of Health and Soc. Behavior* (Dec. 2006), <https://pubmed.ncbi.nlm.nih.gov/17240927/>.
- 164 Congress’ directions regarding the issuance of standards for the privacy of IIHI are codified at [42 U.S.C. 1320d-2](#) note. See also [45 CFR 160.104\(a\)](#).
- 165 Dep’t of Defense, Memorandum Re: Ensuring Access to Reproductive Health Care, at 1 (Oct. 20, 2022) (removed emphasis on “not” in original), <https://media.defense.gov/2022/Oct/20/2003099747/-1/-1/1/MEMORANDUM-ENSURING-ACCESS-TO-REPRODUCTIVE-HEALTH-CARE.PDF>.
- 166 Kristin Cohen, “Location, health, and other sensitive information: FTC committed to fully enforcing the law against illegal use and sharing of highly sensitive data”, *Federal Trade Commission Business Blog* (July 11, 2022), <https://www.ftc.gov/business-guidance/blog/2022/07/location-health-and-other-sensitive-information-ftc-committed-fully-enforcing-law-against-illegal> (last accessed Nov. 15, 2022).
- 167 *Id.*
- 168 See Daniel M. Walker et al., “Interoperability in a Post-Roe Era Sustaining Progress While Protecting Reproductive Health Information,” *JAMA* (Nov. 1, 2022) (discussing that segregation of records for reproductive health care is more difficult than for SUD treatment records because “reproductive health services are often provided in the same settings as other primary and acute care and thus could be inferred or directly reflected in many parts of the record.”), <https://jamanetwork-com.ezproxyhhs.nihlibrary.nih.gov/journals/jama/fullarticle/2797865>; See, e.g., [87 FR 74216, 74221 \(Dec. 2, 2022\)](#) (noting that 42 CFR part 2 previously resulted in the separation of SUD treatment records previous from other health records, which led to the creation of data “silos” that hampered the integration of SUD treatment records into covered entities’ electronic record systems and billing processes. When considering amendments to the relevant statute, some lawmakers argued that the silos perpetuated negative stereotypes about persons with SUD and inhibited coordination of care during the opioid epidemic.). See also Health Info. Tech. Advisory Comm., “Health Information Technology Advisory Committee (HITAC) Annual Report for Fiscal Year 2019,” 2019 ONC Ann. Rep., at 37 (Feb. 19, 2020), https://www.healthit.gov/sites/default/files/page/2020-03/HITACAnnualReportforFY19_508.pdf

(“The new certification criteria that support the sharing of data via third-party apps will help advance the use of data segmentation, but adoption of this capability by the industry is not yet widespread.”).

- 169 See 88 FR 23746, 23898 (Apr. 18, 2023) (explaining that while there are standards for security labels for document-based exchange that the Office of the National Coordinator for Health Information Technology (ONC) adopted in full in 2020 for the criteria in 45 CFR 170.315(b)(7) and (b)(8) to support the application of security labels at a granular level for sending in and receiving, standards to define the technical requirements for the actions described by the security label vocabularies do not yet exist. In the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule, published in 2020, ONC estimated a cost of the certification criteria and standards adopted for security labels in 45 CFR 170.315(b)(7) and (b)(8). The Department estimated the total cost to developers could range from \$2,910,400 to \$6,933,600 and that it would be a onetime cost. (85 FR 25926) The criteria do not include the ability for health IT to take the actions described by the security labels. Additionally, ONC did not require that health IT be certified to the criteria described above, making it essentially voluntary. Accordingly, the estimates for health IT developer and health care provider costs were likely significantly lower than they would have been if health IT were required to be certified to the criteria for participation. Thus, the total cost of implementing full segmentation capabilities is likely substantially higher than the per-product cost estimates provided by the Department in that rule). See also 88 FR 23746, 23875 (Apr. 18, 2023) (discussing examples of challenges or technical limitations to electronic health information segmentation that have been described to ONC).
- 170 See 64 FR 59918, at 59924, 59939, and 59955 (Nov. 3, 1999).
- 171 See 42 U.S.C. 1320d-6(a).
- 172 See 42 U.S.C. 1320d-6(b).
- 173 See 42 U.S.C. 1320d-5. See also 45 CFR part 160, subparts A, D, and E.
- 174 Press Release, “Breaking Language Barriers: Biden-Harris Administration Announces New Plan to Address Language Barriers and Strengthen Language Access,” U.S. Dep’t of Health and Human Servs. (Nov. 15, 2023), <https://www.hhs.gov/about/news/2023/11/15/breaking-language-barriers-biden-harris-administration-announces-new-plan-address-language-barriers-strengthen-language-access.html>.
- 175 Press Release, “HHS Issues New Proposed Rule to Strengthen Prohibitions Against Discrimination on the Basis of a Disability in Health Care and Human Services Programs,” U.S. Dep’t of Health and Human Servs. (Sept. 7, 2023), <https://www.hhs.gov/about/news/2023/09/07/hhs-issues-new-proposed-rule-to-strengthen-prohibitions-against-discrimination-on-basis-of-disability-in-health-care-and-human-services-programs.html>.
- 176 Press Release, “HHS Issues Proposed Rule to Advance Non-discrimination in Health and Human Service Programs for LGBTQI+ Community,” U.S. Dep’t of Health and Human Servs. (July 11, 2023), <https://www.hhs.gov/about/news/2023/07/11/hhs-issues-proposed-rule-advance-non-discrimination-health-human-service-programs-lgbtqi-community.html>.
- 177 Press Release, “HHS Announces Proposed Rule to Strengthen Nondiscrimination in Health Care,” U.S. Dep’t of Health and Human Servs. (July 25, 2022), <https://www.hhs.gov/about/news/2022/07/25/hhs-announces-proposed-rule-to-strengthen-nondiscrimination-in-health-care.html>.
- 178 See 42 U.S.C. 1320d note.
- 179 See 42 U.S.C. 1320d-2 note.
- 180 See 45 CFR 164.512(f)(1)(ii)(C).

- 181 See, e.g., [45 CFR 164.512\(f\)](#) and [164.514\(d\)\(3\)\(iii\)](#).
- 182 See [45 CFR 164.502\(g\)](#) (describing personal representatives) and [164.524\(a\)\(3\)](#) (describing reviewable grounds for denial of access to PHI by a personal representative).
- 183 Off. for Civil Rights, “Health Information Privacy,” U.S. Dep’t of Health and Human Servs., <https://www.hhs.gov/hipaa/index.html>.
- 184 See [42 U.S.C. 1320d-1320d-8](#).
- 185 [45 CFR 160.103](#).
- 186 See section 1101(3) of Public Law 74-271, 49 Stat. 620 (Aug. 14, 1935) (codified at [42 U.S.C. 1301\(3\)](#)).
- 187 [1 U.S.C. 8\(a\)](#). The Department is not opining on whether any state law confers a particular legal status upon a fertilized egg, embryo, or fetus. Rather, the Department cites to this statute to help define the scope of privacy protections that attach pursuant to HIPAA and its implementing regulations.
- 188 [Id.](#)
- 189 [88 FR 23506, 23523 \(Apr. 17, 2023\)](#).
- 190 [45 CFR 160.103](#) (definition of “Individual”).
- 191 See Sharon T. Phelan, “The Prenatal Record and the Initial Prenatal Visit,” *The Glob. Libr. of Women's Med.* (last updated Jan. 2008) (PHI about the fetus is included in the mother's PHI), <https://www.glowm.com/section-view/heading/ThePrenatalRecordandtheInitialPrenatalVisit/item/107#.Y7WRKofMKU1>.
- 192 See [42 U.S.C. 1320d](#).
- 193 [45 CFR 160.103](#) (definition of “Person”). The Department first defined the term “person” in the HIPAA Rules as part of the 2003 Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings Interim Final Rule (2003 Interim Final Rule) to distinguish a “natural person” who could testify in the context of administrative proceedings from an “entity” (defined therein as a “legal person”) on whose behalf a person would testify. See [45 CFR 160.502](#) of the 2003 Interim Final Rule, [68 FR 18895, 18898 \(Apr. 17, 2003\)](#) (Person is defined to mean a natural person or a legal person).
- 194 [45 CFR 160.103](#) (definition of “Individual”). The definition of “individual” in the HIPAA Rules was first adopted in the 2000 Privacy Rule.
- 195 See [45 CFR 164.512\(c\)\(1\)](#). This provision explicitly excludes reports of child abuse, which are addressed by [45 CFR 164.512\(b\)\(1\)](#).
- 196 [1 U.S.C. 8\(a\)](#).
- 197 Public Law 110-233, 122 Stat. 881. See generally Off. for Civil Rights, “Health Information Privacy, Genetic Information,” U.S. Dep’t of Health and Human Servs. (Content last reviewed June 16, 2017), <https://www.hhs.gov/hipaa/for-professionals/special-topics/genetic-information/index.html#:~:text=TheGeneticInformationNondiscriminationAct,intotwosections/orTitles>.
- 198 See [45 CFR 164.524](#). See also William Baude & Stephen E. Sachs, “The Law of Interpretation,” 130 *Harv. L. Rev.* 1079 (2017).

199 45 CFR 164.502(g).

200 See 45 CFR 164.512(j)(1)(i).

201 42 U.S.C. 1320d-7(a)

202 42 U.S.C. 1320d-7(b).

203 45 CFR 164.501 (definition of “Public health authority”).

204 45 CFR 164.514(h).

205 This is unchanged by this final rule.

206 See 45 CFR 164.512(b). The Privacy Rule addresses its interactions with laws governing excepted public health activities in two sections: 45 CFR 164.512(a), Standard: Uses and disclosures required by law, and 45 CFR 164.512(b), Standard: Uses and disclosures for public health activities.

207 45 CFR 164.512(b).

208 45 CFR 164.512(f).

209 88 FR 23506, 23523 (Apr. 17, 2023).

210 The 1996-98 Report of the NCVHS to the Secretary describes various types of activities considered to be public health during the era in which HIPAA was enacted, such as the collection of public health surveillance data on health status and health outcomes and vital statistics information. See Nat'l Comm. On Vital and Health Stats., Report of The National Committee on Vital and Health Statistics, 1996-98, (Dec. 1999), <https://ncvhs.hhs.gov/wp-content/uploads/2018/03/90727nv-508.pdf>.

211 *Id.*

212 *Id.*

213 Richard N. Danila et al., “Legal Authority for Infectious Disease Reporting in the United States: Case Study of the 2009 H1N1 Influenza Pandemic,” 105 a.m. J. Public Health 13 (Jan. 2015).

214 See “Reportable Diseases,” MedlinePlus, <https://medlineplus.gov/ency/article/001929.htm> (accessed Oct. 19, 2022). See also Nat'l Notifiable Diseases Surveillance Sys., “What is Case Surveillance?,” Ctrs. for Disease Control and Prevention (July 20, 2022), <https://www.cdc.gov/nndss/about/index.html>.

215 See “Reportable Diseases,” *supra* note 215. Such reporting is a type of public health surveillance activity.

216 See Victims Rts. Law Ctr., “Mandatory Reporting of Non-Accidental Injuries: A State-by-State Guide” (May 2014), <http://4e5ae7d17e.nxcli.net/wp-content/uploads/2021/01/Mandatory-Reporting-of-Non-Accidental-Injury-Statutes-by-State.pdf>.

217 See, e.g., 38 U.S.C. 1110 (referring to an “injury suffered or disease contracted”); 10 U.S.C. 972 (discussing time lost as a result of “disease or injury”); 38 U.S.C. 3500 (providing education for certain children whose parent suffered “a disease or injury” incurred or aggravated in the Armed Forces); see also 5 U.S.C. 8707 (insurance provision discussing compensation as a result of “disease or injury”); 33 U.S.C. 765 (discussing retirement for disability as a result of “disease or injury”); 15 U.S.C. 2607(c) (requiring chemical manufacturers to maintain records of “occupational disease or injury”).

- 218 45 CFR 164.512(b)(ii).
- 219 See 65 FR 82462, 82571 (Dec. 28, 2000) (recognizing that “disease management activities” often constitute “health care” under HIPAA); *Id.* at 82777 (discussing the importance of privacy for information about cancer, a “disease” that causes an “indisputable” “societal burden”); *Id.* at 82778 (discussing the importance of privacy for information about sexually transmitted diseases, including Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS)); *Id.* at 82463-64 (noting that numerous states adopted laws protecting health information relating to certain health conditions such as communicable diseases, cancer, HIV/AIDS, and other stigmatized conditions.); *Id.* at 82731 (finding that there are no persuasive reasons to provide information contained within disease registries with special treatment as compared with other information that may be used to make decisions about an individual).
- 220 See, e.g., 65 FR 82462, 82517 (Dec. 28, 2000) (discussing tort litigation as information that could implicate IIHI); *Id.* at 82542 (discussing workers' compensation); *Id.* at 82527 (separately addressing disclosures about “abuse, neglect or domestic violence” and limiting such disclosures to only two circumstances, even if expressly authorized by state statute or regulation).
- 221 See “Public Health Professionals Gateway, Public Health Systems & Best Practices, Health Department Governance,” Ctrs. for Disease Control and Prevention (Nov. 25, 2022), <https://www.cdc.gov/publichealthgateway/sitesgovernance/index.html>.
- 222 See the list of events included in vital events, Nat'l Ctr. for Health Stats., “About the National Vital Statistics System,” Ctrs. for Disease Control and Prevention (Jan. 4, 2016), https://www.cdc.gov/nchs/nvss/about_nvss.htm.
- 223 See Nat'l Ctr. for Health Stats., “Birth Data,” Ctrs. for Disease Control and Prevention (Dec. 6, 2022), <https://www.cdc.gov/nchs/nvss/births.htm>.
- 224 See Ctrs. For Disease Control and Surveillance, “How Tracking Deaths Protects Health,” (July 2018), <https://www.cdc.gov/surveillance/pdfs/Tracking-Deaths-protects-healthh.pdf>.
- 225 See Nat'l Ctr. for Health Stats., Ctrs. for Disease Control and Prevention, “State Definitions and Reporting Requirements: For Live Births, Fetal Deaths, and Induced Terminations of Pregnancy,” at 5 (1997), <https://www.cdc.gov/nchs/data/misc/itop97.pdf>.
- 226 Nat'l Ctr. for Health Stats., Ctrs. for Disease Control and Prevention, “Model State Vital Statistics Act and Regulations,” at 8 (1992), <https://www.cdc.gov/nchs/data/misc/mvsact92b.pdf>.
- 227 42 U.S.C. 1178(b) (codified in HIPAA at 42 U.S.C. 1320d-7).
- 228 Section 1178(a) of HIPAA.
- 229 See 45 CFR 164.512(b)(1)(i); Off. for Civil Rights, “Disclosures for Public Health Activities,” U.S. Dep't of Health and Human Servs., <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-public-health-activities/index.html> (accessed Oct. 19, 2022).
- 230 See “Introduction to Public Health Surveillance,” Ctrs. for Disease Control and Prevention (Nov. 15, 2018), <https://www.cdc.gov/training/publichealth101/surveillance.html>.
- 231 See “Public Health Professionals Gateway, Ten Essential Public Health Services,” Ctrs. for Disease Control and Prevention (Dec. 1, 2022), <https://www.cdc.gov/publichealthgateway/publichealthservices/essentialhealthservices.html>.
- 232 Section 1178(a) of SSA.

- 233 “Health, Public Health,” Black’s Law Dictionary (11th ed. 2019).
- 234 “Public Health,” Stedman’s Medical Dictionary 394520.
- 235 Jonathan Weinstein, In Re Miguel M., 55 N.Y.L. Sch. L. Rev. 389, 390 (2010) (citing Stephen B. Thacker, “Historical Development,” in Principles and Practice of Public Health Surveillance 1 (Steven M. Teutsch & R. Elliott Churchill eds., 2d ed., 2000)), https://digitalcommons.nyls.edu/cgi/viewcontent.cgi?article=1599&context=nyls_law_review.
- 236 See, e.g., Richard A. Goodman et al., “Forensic Epidemiology: Law at the Intersection of Public Health and Criminal Investigations,” 31 J. of Law, Med. & Ethics 684, 689-90 (2003); *La. Rev. Stat. Ann. Sec. 40:3.1* (2011) (defining threats to public health as nuisances “including but not limited to communicable, contagious, and infectious diseases, as well as illnesses, diseases, and genetic disorders or abnormalities”); *N.C. Gen. Stat. sec. 130A-141.1(a)* (2010) (defining public health investigations as the “surveillance of an illness, condition, or symptoms that may indicate the existence of a communicable disease or condition”).
- 237 See, e.g., *65 FR 82462, 82464* (Dec. 28, 2000) (noting that reporting of public health information on communicable diseases is not prevented by individuals’ right to information privacy); *Id. at 82467* (discussing the importance of accurate medical records in recognizing troubling public health trends and in assessing the effectiveness of public health efforts); *Id. at 82473* (discussing disclosure to “a department of public health”); *Id. at 82525* (recognizing that it may be necessary to disclose PHI about communicable diseases when conducting a public health intervention or investigation); *Id. at 82526* (recognizing that an entity acts as a “public health authority” when, in its role as a component of the public health department, it conducts infectious disease surveillance); Stephen B. Thacker, Epidemiology Program Office, Ctrs. for Disease Control and Prevention, “HIPAA Privacy Rule and Public Health: Guidance from CDC and the U.S. Department of Health and Human Services,” 52 MMWR 1 (Apr. 11, 2003), <https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm> (describing what traditionally are considered to be “public health activities” that require PHI).
- 238 See Miguel M. v. Barron, 950 NE2d 107, at 111 (2011) (explaining “[t]he apparent purpose of the public health exception is to facilitate government activities that protect large numbers of people from epidemics, environmental hazards, and the like, or that advance public health by accumulating valuable statistical information.”).
- 239 *88 FR 23510, 23525* (Apr. 17, 2023).
- 240 See Miguel M. v. Barron at 111, supra note 239 (concluding that “[t]o disclose private information about particular people, for the purpose of preventing those people from harming themselves or others, effects a very substantial invasion of privacy without the sort of generalized public benefit that would come from, for example, tracing the course of an infectious disease.”).
- 241 For example, traditional public health reporting laws grew from colonial requirements that physicians report disease. These requirements transitioned to state regulatory requirements imposed by public health departments on authority granted to them by states. See Ctrs. for Disease Control and Prevention, “Public Health Law 101, Disease Reporting and Public Health Surveillance,” at 12 and 14 (Jan. 16, 2009), <https://www.cdc.gov/phlp/docs/phl101/PHL101-Unit-5-16Jan09-Secure.pdf>. See also, e.g., *Code of Georgia 31-12-2* (2021) (authority to require disease reporting).
- 242 See “Public Health,” supra note 235 (“Many cities have a ‘public health department’ or other agency responsible for maintaining the public health; Federal laws dealing with health are administered by the Department of Health and Human Services.”); see also “Forensic Epidemiology: Law at the Intersection of Public Health and Criminal Investigations,” supra note 237, at 689.
- 243 See *Camara v. Municipal Ct. of City & Cty. of S.F.*, 387 U.S. 523, 535-37 (1967) (discussing administrative inspections under the Fourth Amendment, such as those aimed at addressing “conditions which are hazardous to public health and safety,” and not “aimed at the discovery of evidence of crime”); *42 U.S.C. 241(d)(D)* (prohibiting disclosure of private

information from research subjects in “criminal” and other proceedings); 42 U.S.C. 290dd-2(c) (prohibiting substance abuse records from being used in criminal proceedings).

- 244 See “Forensic Epidemiology: Law at the Intersection of Public Health and Criminal Investigations,” *supra* note 237, at 687 (discussing reasons why “an association of public health with law enforcement” may be “to the detriment of routine public health practice”). See also 45 CFR 164.512(b)(1)(i) (including “public health investigations” as an activity carried out by a public health authority that is authorized by law to carry out public health activities).
- 245 See “Improving the Role of Health Departments in Activities Related to Abortion,” *Am. Pub. Health Ass’n* (Oct. 26, 2021), <https://www.apha.org/Policies-and-Advocacy/Public-Health-Policy-Statements/Policy-Database/2022/01/07/Improving-Health-Department-Role-in-Activities-Related-to-Abortion>.
- 246 See “Reportable diseases,” *supra* note 215. See also “What is Case Surveillance?,” *supra* note 215.
- 247 See “Reproductive Health, About Us,” *Ctrs. for Disease Control and Prevention* (Apr. 20, 2022), <https://www.cdc.gov/reproductivehealth/drh/about-us/index.htm>; and “Reproductive Health, CDCs Abortion Surveillance System FAQs,” *Ctrs. for Disease Control and Prevention* (Nov. 17, 2022), https://www.cdc.gov/reproductivehealth/data_stats/abortion.htm.
- 248 See 45 CFR 164.502(b).
- 249 See 45 CFR 164.514(a).
- 250 45 CFR 164.514(d)(3)(iii)(A); see also 45 CFR 164.514(h)(2)(ii) and (iii).
- 251 See 45 CFR 164.512(b)(1)(ii).
- 252 See 45 CFR 164.502(b) and 164.514(d).
- 253 65 FR 82462, 82527 (Dec. 28, 2000).
- 254 Public Law 101-647, 104 Stat. 4789 (codified at 18 U.S.C. 3509).
- 255 Public Law 93-247, 88 Stat. (codified at 42 U.S.C. 5101 note).
- 256 See 34 U.S.C. 20341(a)(1), originally enacted as part of the Victims of Child Abuse Act of 1990 and codified at 42 U.S.C. 13031, which was editorially reclassified as 34 U.S.C. 20341, Crime Control and Law Enforcement. For the purposes of such mandated reporting, see 34 U.S.C. 20341(c)(1) for definition of “child abuse.”
- 257 88 FR 23506, 23526 (Apr. 17, 2023).
- 258 65 FR 82462, 82527 (Dec. 28, 2000).
- 259 See 45 CFR 164.502(g).
- 260 See 45 CFR 164.502(b) and 164.514(d).
- 261 See 45 CFR 164.512(e) and (f).
- 262 See 45 CFR 164.512(e) and (f).
- 263 65 FR 82462, 82527 (Dec. 28, 2000).
- 264 45 CFR 160.103 (definition of “Health care”).

- 265 These groupings are (1) “[p]reventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body” and (2) “[the s]ale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.” It would also include supplies purchased over the counter or furnished to the individual by a person that does not meet the definition of a health care provider under the HIPAA Rules. 45 CFR 164.103 (definition of “Health care provider”).
- 266 88 FR 23506, 23527-28 (Apr. 17, 2023).
- 267 88 FR 23506, 23527 (Apr. 17, 2023).
- 268 65 FR 82571 (Dec. 28, 2000).
- 269 See “What is Assisted Reproductive Technology?” Centers for Disease Control and Prevention (Oct. 8, 2019), <https://www.cdc.gov/art/whatis.html> and “Fact Sheet: In Vitro Fertilization (IVF) Use Across the United States,” U.S. Dep’t of Health and Human Servs. (Mar. 13, 2024), <https://www.hhs.gov/about/news/2024/03/13/fact-sheet-in-vitro-fertilization-ivf-use-across-united-states.html>.
- 270 45 CFR 160.103 (definition of “Protected health information”).
- 271 88 FR 23506, 23528 (Apr. 17, 2023).
- 272 88 FR 23506, 23528-29 (Apr. 17, 2023).
- 273 42 U.S.C. 17935(e).
- 274 In the preamble to the 2000 Privacy Rule, we explained that a covered entity could meet HIPAA plain language requirements by organizing material to serve the reader; writing short sentences in the active voice; using pronouns; using common, everyday language; and dividing material into short sections. 65 FR 82462, 82548 (Dec. 28, 2000).
- 275 89 FR 1192, 1302 (Jan. 9, 2024). See also Off. for Civil Rights, “Information Blocking Regulations Work In Concert with HIPAA Rules and Other Privacy Laws to Support Health Information Privacy,” U.S. Dep’t of Health and Human Servs. (Apr. 12, 2023), <https://www.healthit.gov/buzz-blog/information-blocking/information-blocking-regulations-work-in-concert-with-hipaa-rules-and-other-privacy-laws-to-support-health-information-privacy>.
- 276 See, e.g., Off. for Civil Rights, “Resource for Health Care Providers on Educating Patients about Privacy and Security Risks to Protected Health Information when Using Remote Communication Technologies for Telehealth,” U.S. Dep’t of Health and Human Servs., <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/resource-health-care-providers-educating-patients/index.html>.
- 277 See 45 CFR 164.502(a)(3) and (e). See also 45 CFR 164.504(e).
- 278 For information about what a business associate is and the requirements for business associate agreements, see Off. for Civil Rights, “Business Associate Contracts,” U.S. Dep’t of Health and Human Servs. (Jan. 25, 2013), <https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html>.
- 279 Off. for Civil Rights, “Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet,” U.S. Dep’t of Health and Human Servs. (June 29, 2022), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html>.
- 280 88 FR 23506, 23529-33 (Apr. 17, 2023).

281 The Department does not oppose efforts to implement or employ technology that is capable of segmenting data. Rather, the Department's proposal was informed by the recognition that the technology deployed by most regulated entities today is not capable of doing so.

282 See *supra* discussion of “Public health” for more information on what constitutes a “public health activity” under the Privacy Rule.

283 [88 FR 23506, 23532 \(Apr. 17, 2023\)](#).

284 [Id. at 23510, 23522](#), and [23531](#).

285 See *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Eisenstadt v. Baird*, 405 U.S. 438 (1972); *Dobbs*, 597 U.S. 345 (Kavanaugh, J., concurring) (*Dobbs* “does not threaten or cast doubt on” the precedents providing constitutional protection for contraception).

286 See proposed [45 CFR 164.502\(a\)\(5\)\(iii\)\(D\)](#). See also [88 FR 23506, 23552-53 \(Apr. 17, 2023\)](#).

287 [Section 164.502\(a\)\(5\)\(iii\)\(A\)\(3\)](#) incorporates the same language by reference to [45 CFR 164.502\(a\)\(5\)\(iii\)\(A\)\(1\)](#) and [\(A\)\(2\)](#).

288 [42 U.S.C. 1320d-7\(a\)\(1\)](#) (providing the general rule that, with limited exceptions, a provision or requirement under HIPAA supersedes any contrary provision of state law); see also section 264(c)(2) of Public Law 104-191 (codified at [42 U.S.C. 1320d-2](#) note) and [45 CFR 160.203](#).

289 See final [45 CFR 164.509](#), and discussion below.

290 See [42 U.S.C. 1320d-6](#).

291 [88 FR 23506, 23532-33 \(Apr. 17, 2023\)](#).

292 See [45 CFR 164.512\(d\)\(1\)\(i\) through \(iv\)](#) for health oversight activities for which the Privacy Rule permits uses and disclosures of PHI. See also the National Association of Medicaid Fraud Control Units, described at <https://www.naag.org/about-naag/namfcu/>. All 53 federally certified Medicaid Fraud Control Units voluntarily subscribe to this organization. This final rule does not interfere with any State's ability to meet their statutory obligations to combat health care fraud related to Medicaid.

293 [31 U.S.C. 3729-3733](#).

294 [18 U.S.C. 248\(e\)\(5\)](#) (definition of “Reproductive health services”).

295 [45 CFR 160.103](#) (definition of “Person”).

296 Note that in Section V.A.1, the Department is clarifying the definition of “person,” although that clarification does not affect the analysis in this paragraph.

297 See [45 CFR 164.514\(d\)\(3\)\(iii\)\(A\)](#) and [65 FR 82462, 82545](#), and [82547 \(Dec. 28, 2000\)](#).

298 [45 CFR 164.514\(h\)\(2\)](#) and [65 FR 82462, 82546-47 \(Dec. 28, 2000\)](#).

299 See [45 CFR 164.514\(h\)](#) and [65 FR 82462, 82546-47 \(Dec. 28, 2000\)](#).

300 See [65 FR 82462, 82545 \(Dec. 28, 2000\)](#) (“[. . .] covered entities making disclosures to public officials that are permitted under § 164.512 may rely on the representations of a public official that the information requested is the minimum necessary.”); see also [id. at 82547](#) (further discussing verification of identity and authority of persons requesting PHI

in 45 CFR 164.514(h) and the requirements in 45 CFR 164.512 for the circumstances under which covered entities must make reasonable determinations about the sufficiency of proof of identify and authority based on documentary evidence, contrasted with a reasonable reliance on verbal representations when necessary to avert a pending emergency or imminent threat to the health or safety of a person or the public pursuant to 45 CFR 164.512(j)(1)(i).

301 See 88 FR 23506, 23530 (Apr. 17, 2023).

302 See 42 CFR part 2 and the 2024 Part 2 Rule for more information about Part 2 and the protections afforded to Part 2 records.

303 See the finalized definition of “Reproductive health care” at 45 CFR 160.103.

304 See Off. for Civil Rights, “Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet,” U.S. Dep’t of Health and Human Servs. (June 29, 2022), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html>.

305 See 45 CFR 164.502(b). Uses and disclosures of PHI pursuant to 45 CFR 164.512(a) are limited to the relevant requirements of such law. 45 CFR 164.512(a)(1).

306 45 CFR 164.514(b).

307 See 45 CFR 164.506.

308 See 45 CFR 160.103 (definitions of “health plan” and “group health plan”).

309 In the 2023 Privacy Rule NPRM, we proposed the Scope of prohibition in 45 CFR 164.502(a)(5)(iii)(B).

310 88 FR 23506, 23509 (Apr. 17, 2023) (citing 65 FR 82464 (Dec. 28, 2000)).

311 Id.

312 See 42 U.S.C. 1320d-5 and 6.

313 See 45 CFR 164.512(a).

314 See 45 CFR 164.512(a).

315 Public Law 100-578, 102 Stat. 2903 (Oct. 31, 1988) (codified at 42 U.S.C. 201 note).

316 See 45 CFR 164.512(a)(1).

317 See 45 CFR 164.103 (definition of “Required by law”). The definition provides additional explanation about what constitutes a mandate contained in law.

318 See 45 CFR 164.512(a)(1).

319 See 45 CFR 164.103 (definition of “Required by law”).

320 The Privacy Rule permits but does not require covered entities to disclose PHI in response to an order of a court or administrative tribunal. The Privacy Rule also permits but does not require covered entities to disclose PHI in response to a subpoena, discovery request, or other lawful process, but only when certain conditions are met. See 45 CFR 164.512(e)(1). These provisions cannot be used to make disclosures to law enforcement officials that are restricted by 45 CFR 164.512(f). See 45 CFR 164.512(e)(2).

- 321 45 CFR 164.512(f)(1).
- 322 Whether the regulated entity is limited by the minimum necessary standard or the relevant requirements of the law that requires the reporting depends upon whether the regulated entity is making the disclosure pursuant to 45 CFR 164.512(a) or some other permission under 45 CFR 164.512. See 45 CFR 164.502(b)(v).
- 323 See 45 CFR 164.502(g).
- 324 See 45 CFR 164.502(g)(3)(i). See also Off. for Civil Rights, “Personal Representatives,” U.S. Dep’t of Health and Human Servs., <https://www.hhs.gov/hipaa/for-individuals/personal-representatives/index.html>.
- 325 See, e.g., 45 CFR 164.510(b)(3) and 164.512(j)(1)(i)(A).
- 326 See 65 FR 82462, 82471 (Dec. 28, 2000).
- 327 88 FR 23506, 23533-34 (Apr. 17, 2023).
- 328 See 45 CFR 164.502(g).
- 329 See 45 CFR 164.502(g)(3)(i).
- 330 88 FR 23506, 23534 (Apr. 17, 2023).
- 331 45 CFR 164.506.
- 332 45 CFR 164.508.
- 333 45 CFR 164.510.
- 334 45 CFR 164.512.
- 335 45 CFR 164.508(b).
- 336 88 FR 23506, 23534-37 (Apr. 17, 2023).
- 337 Pursuant to 45 CFR 164.530(j), regulated entities would be required to maintain a written or electronic copy of the attestation.
- 338 The Federal plain language guidelines under the Plain Writing Act of 2010 only applies to Federal agencies, but it serves as a helpful resource. See 5 U.S.C. 105 and “Federal plain language guidelines,” U.S. Gen. Servs. Admin., <https://www.plainlanguage.gov/guidelines/>.
- 339 Proposed 45 CFR 164.509(b)(1)(iv) and (c)(1)(iv).
- 340 While not explicitly stated in the Privacy Rule, the Department previously issued guidance clarifying that authorizations are permitted to be submitted and signed electronically. See Off. for Civil Rights, “Is a copy, facsimile, or electronically transmitted version of a signed authorization valid under the Privacy Rule?,” U.S. Dep’t of Health and Human Servs., HIPAA FAQ #475 (Jan. 9, 2023), <https://www.hhs.gov/hipaa/for-professionals/faq/475/is-a-copy-of-a-signed-authorization-valid/index.html> and Off. for Civil Rights, “How do HIPAA authorizations apply to an electronic health information exchange environment?,” U.S. Dep’t of Health and Human Servs., HIPAA FAQ #554 (July 26, 2013), <https://www.hhs.gov/hipaa/for-professionals/faq/554/how-do-hipaa-authorizations-apply-to-electronic-health-information/index.html>.
- 341 This approach is consistent with 45 CFR 164.514(h), which requires a regulated entity to verify the identity and legal authority of a public official or a person acting on behalf of a public official, and describes the type of documentation

upon which a regulated entity may rely, if such reliance is reasonable under the circumstances, to do so. See also 45 CFR 164.514(d)(3)(iii)(A), which permits a covered entity to rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s).

342 Proposed 45 CFR 164.509(d).

343 Business associates became directly liable for compliance with certain requirements of the HIPAA Rules under the HITECH Act. Consistent with the HITECH Act, the 2013 Omnibus Rule identified the portions of the HIPAA Rules that apply directly to business associates and for which business associates are directly liable. Prior to the HITECH Act and the Omnibus Rule, these requirements applied to business associates and their subcontractors indirectly through the requirements under 45 CFR 164.504(e) and 164.314(a), which require that covered entities by contract require business associates to limit uses and disclosures and implement HIPAA Security Rule-like safeguards. See 78 FR 5566 (Jan. 25, 2013). See also Off. for Civil Rights, “Direct Liability of Business Associates Fact Sheet,” U.S. Dep’t of Health and Human Servs. (July 16, 2021), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html>.

344 45 CFR 164.504(e) and 164.314(a).

345 45 CFR 164.504(e)(2)(i)(E).

346 65 FR 82462, 82471, and 82875 (Dec. 28, 2000).

347 See 42 U.S.C. 1320d-6(a).

348 45 CFR 164.509(b)(1)(iii) and (c)(1)(vi).

349 45 CFR 164.502(b). The minimum necessary standard of the Privacy Rule applies to all uses and disclosures where a request does not meet one of the specified exceptions in paragraph (b)(2).

350 45 CFR 164.502(b)(1).

351 This approach is consistent with 45 CFR 164.514(h), which requires a covered entity to verify the identity and legal authority of a public official or a person acting on behalf of the public official and describes the type of documentation upon which regulated entities can rely, if such reliance is reasonable under the circumstances, to do so. See also 45 CFR 164.514(d)(3)(iii)(A), which permits a covered entity to rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s).

352 E.g., Restatement (Second) Torts § 283, comment b (Am. L. Inst. 1965).

353 45 CFR 164.509(d).

354 See 42 U.S.C. 1320d-6(a).

355 A person (including an employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in section 1320d-9(b)(3) of this title) and the individual obtained or disclosed such information without authorization. *Id.*

356 See 42 U.S.C. 1320d-6(b).

- 357 45 CFR 164.400 et seq. The HIPAA Breach Notification Rule, 45 CFR 164.400-414, requires HIPAA covered entities and their business associates to provide notification following a breach of unsecured PHI.
- 358 See 42 U.S.C. 1320d-6(a).
- 359 See 45 CFR 164.512.
- 360 See 42 U.S.C. 300jj-52(a)(1) (excluding from the definition of “information blocking” practices that are likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information if they are “required by law”; 85 FR 25642, 25794 (May 1, 2020) (explaining that “required by law” specifically refers to interferences that are explicitly required by state or Federal law). See also 89 FR 1192, 1351 (Jan. 9, 2024) (affirming that where applicable law prohibits access, exchange, or use of information, practices in compliance with such law are not considered to be information blocking and citing to compliance with the Privacy Rule as an example of an applicable law).
- 361 This approach is consistent with 45 CFR 164.514(h), which requires a regulated entity to verify the identity and legal authority of a public official or a person acting on behalf of the public official and describes the type of documentation upon which the regulated entity can rely, if such reliance is reasonable under the circumstances, to do so. See also 45 CFR 164.514(d)(3)(iii)(A), which permits a covered entity to rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s).
- 362 45 CFR 164.514(h)(1) requires a regulated entity to verify both the identity of the person requesting PHI and the authority of any such person to have access to PHI, if the identity or authority of such person is not known to the regulated entity. 45 CFR 164.514(h)(2)(ii) describes the information upon which a regulated entity may rely, if such reliance is reasonable under the circumstances, to verify the identity of a public official requesting PHI or a person acting on behalf of a public official, while 45 CFR 164.514(h)(2)(iii) describes the information upon which a regulated entity may rely, if such reliance is reasonable under the circumstances, to verify the authority of the public official requesting PHI or a person acting on behalf of a public official.
- 363 45 CFR 164.512(e)(1)(ii)(A).
- 364 45 CFR 164.512(e)(1)(ii)(B).
- 365 45 CFR 164.512(e)(1)(iii) and (iv).
- 366 See 42 U.S.C. 1320d-6(a).
- 367 See 42 U.S.C. 1320d-5. See also 45 CFR part 160, subparts A, D, and E.
- 368 See 42 U.S.C. 1320d-6(b).
- 369 See 45 CFR 164.514(h); see also 65 FR 82462, 82541, and 82547 (Dec. 28, 2000).
- 370 45 CFR 164.514(h)(2)(iii)(A).
- 371 45 CFR 164.514(h)(2)(iii)(B).
- 372 45 CFR 164.512(a)(1).
- 373 45 CFR 164.514(d)(3)(iii)(A).

374 42 U.S.C. 1320d-5.

375 42 U.S.C. 1320d-6.

376 45 CFR 165.512(e)(1)(ii).

377 45 CFR 164.512(f)(1)(ii)(C).

378 See 42 U.S.C. 1320d-6(a).

379 65 FR 82462, 82524 (Dec. 28, 2000).

380 See *id.* at 82471.

381 88 FR 23506, 23537-38 (Apr. 17, 2023).

382 45 CFR 164.512(d).

383 45 CFR 164.512(e).

384 45 CFR 164.512(f).

385 45 CFR 164.512(g)(1).

386 The Privacy Rule only applies to PHI, which is IIHI that is maintained or transmitted by, for, or on behalf of a covered entity. Thus, it does not apply to individuals' health information when it is in the possession of a person that is not a regulated entity, such as a friend, family member, or is stored on a personal cellular telephone or tablet. See Off. for Civil Rights, "Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet," U.S. Dep't of Health and Human Servs. (June 29, 2022), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html>.

387 45 CFR 164.512(d).

388 45 CFR 164.512(e).

389 45 CFR 164.512(f).

390 45 CFR 164.512(g)(1).

391 88 FR 23506, 23538 (Apr. 17, 2023).

392 *Id.*

393 45 CFR 164.512(c).

394 See 45 CFR 164.502(b) and 164.514(d).

395 See 45 CFR 164.512(e) and (f).

396 88 FR 23506, 23538-39 (Apr. 17, 2023).

397 See 65 FR 82462, 82531 (Dec. 28, 2000).

398 See U.S. Senate Committee on Finance News Release (Dec. 12, 2023), <https://www.finance.senate.gov/chairmans-news/wyden-jayapal-and-jacobs-inquiry-finds-pharmacies-fail-to-protect-the-privacy-of-americans-medical-records-hhs-must-update-health-privacy-rules> (describing legislative inquiry

into pharmacy chains and release of health information in response to law enforcement). See also Letter from Sen. Wyden and Reps. Jayapal and Jacobs to HHS Sec'y Xavier Becerra (Dec. 12, 2023), https://www.finance.senate.gov/imo/media/doc/hhs_pharmacy_surveillance_letter_signed.pdf (describing findings from Congressional oversight, including survey of chain pharmacies about their processes for responding to law enforcement requests for PHI).

399 See U.S. Senate Committee on Finance News Release, *supra* note 399 and Letter from Sen. Wyden and Reps. Jayapal and Jacobs, *supra* note 399; see also Remy Tumin, “Pharmacies Shared Patient Records Without a Warrant, an Inquiry Finds,” *The New York Times* (Dec. 13, 2023), <https://www.nytimes.com/2023/12/13/us/pharmacy-records-abortion-privacy.html>.

400 See 65 FR 82462, 82531 (Dec. 28, 2000).

401 Public Law 93-579, 88 Stat. 1896 (Dec. 31, 1974) (codified at 5 U.S.C. 552a).

402 Off. for Civil Rights, “Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule: A Guide for Law Enforcement,” https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/emergency/final_hipaa_guide_law_enforcement.pdf.

403 88 FR 23506, 23539 (Apr. 17, 2023).

404 45 CFR 164.520. Unlike many provisions of the Privacy Rule, 45 CFR 164.520 applies only to covered entities, as opposed to both covered entities and their business associates.

405 86 FR 6446 (Jan. 21, 2021).

406 45 CFR 160.103 (definition of “Organized health care arrangement”).

407 88 FR 23506, 23539 (Apr. 17, 2023).

408 89 FR 12472 (Feb. 16, 2024).

409 See also 82 FR 6052, 6082-83 (Jan. 18, 2017); Off. for Civil Rights, “Notice of Privacy Practices for Protected Health Information,” U.S. Dep’t of Health and Human Servs. (July 26, 2013), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/privacy-practices-for-protected-health-information/index.html>.

410 65 FR 82462, 82548-49 (Dec. 28, 2000).

411 Off. for Civil Rights, “Model Notices of Privacy Practices,” U.S. Dep’t of Health and Human Servs. (Apr. 8, 2013), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/model-notices-privacy-practices/index.html>.

412 45 CFR 164.502(d)(2).

413 See 45 CFR part 160, subpart B—Preemption of State Law.

414 58 FR 51735 (Oct. 4, 1993).

415 88 FR 21879 (Apr. 11, 2023).

416 76 FR 3821 (Jan. 21, 2011).

417 Public Law 96-354, 94 Stat. 1164 (codified at 5 U.S.C. 601-612).

418 Public Law 104-4, 109 Stat. 48 (codified at 2 U.S.C. 1501).

419 *Id.* at sec. 202 (codified at 2 U.S.C. 1532(a)).

420 Also referred to as the Congressional Review Act, 5 U.S.C. 801 *et seq.*

421 88 FR 3997 (Jan. 23, 2023).

422 64 FR 59918 (Nov. 3, 1999).

423 78 FR 5566 (Jan. 25, 2013).

424 For each occupation performing activities as a result of the final rule, the Department identifies a pre-tax hourly wage using a database maintained by the Bureau of Labor Statistics. See U.S. Dep't of Labor, "Occupational Employment and Wages" (May 2022), https://www.bls.gov/oes/current/oes_nat.htm.

425 This includes 60 days from publication of a final rule to the effective date and an additional 180 days until the compliance date.

a Number of pharmacy establishments is taken from industry statistics.

426 See U.S. Census Bureau, American Community Survey S0101, AGE AND SEX 2022: ACS 5-Year Estimates Subject Tables (females aged 10-44), <https://data.census.gov/table/ACSST1Y2022.S0101>. The U.S. Census Bureau uses the term "sex" to equate to an individual's biological sex. "Sex—Definition," U.S. Census Bureau (accessed Mar. 20, 2024), <https://www.census.gov/glossary/?term=Sex>.

427 See "Reproductive and Sexual Health," Sexually active females who received reproductive health services (FP-7.1), Healthypeople.gov, <https://wayback.archive-it.org/5774/20220415172039/https://www.healthypeople.gov/2020/leading-health-indicators/2020-lhi-topics/Reproductive-and-Sexual-Health/data>.

428 See American Community Survey S0101, AGE AND SEX 2022: ACS 5-Year Estimates Subject Tables (females aged 10-44), *supra* note 427.

429 See M. Antonia Biggs et al., "Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study," 74(2) JAMA Psychiatry 169, 177 (2017), <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2592320>. See also Julia R. Steinberg et al., "The association between first abortion and first-time non-fatal suicide attempt: a longitudinal cohort study of Danish population registries," 6(12) The Lancet Psychiatry 1031-1038 (Dec. 2019).

430 See Julia R. Steinberg et al., "Fatal flaws in a recent meta-analysis on abortion and mental health," 86(5) Contraception 430-7 (Nov. 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3646711/> (discussing errors and significant shortcomings of the studies included in the 2011 meta-analysis that render its conclusions invalid).

431 See Lawrence O. Gostin et al., "One Year After Dobbs—Vast Changes to the Abortion Legal Landscape," 4(8) JAMA Health Forum (2023), <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2808205> (counting 21 states with post-Dobbs limits that are more restrictive than *Roe v. Wade* allowed) and Laura Deal, "State Laws Restricting or Prohibiting Abortion," Congressional Research Service (Jan. 22, 2024), <https://crsreports.congress.gov/product/pdf/R/R47595>. Because of the pace of change in this area, the Department relies on a higher number than JAMA's 2023 figure as a basis for its cost estimates.

432 See 45 CFR 160.201 *et seq.* for information about exceptions to HIPAA's general preemption authority and the process for requesting such an exception and the criteria for granting it.

- 433 “Information Collection: Process for Requesting Exception Determinations (states or persons),” U.S. Gen. Servs. Admin. & Off. of Mgmt. and Budget, https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=201909-0945-001&icID=10428.
- 434 See *supra*, Table 3 of this RIA.
- 435 *Id.*
- 436 *Id.*
- 437 This includes 60 days from the date of publication to the effective date, plus 120 days from the effective date to the compliance date.
- 438 45 CFR 164.520(c)(1)(v)(A).
- a Totals may not add up due to rounding.
- a Totals may not add up due to rounding.
- 439 See “One Year After Dobbs—Vast Changes to the Abortion Legal Landscape,” *supra* note 432 (counting 21 states with post-Dobbs limits that are more restrictive than *Roe v. Wade* allowed) and “State Laws Restricting or Prohibiting Abortion,” *supra* note 432. Because of the pace of change in this area, the Department relies on a higher number than JAMA's 2023 figure as a basis for its cost estimates.
- 440 See “Trust and Privacy: How Patient Trust in Providers is Related to Privacy Behaviors and Attitudes,” *supra* note 120; Paige Nong et al., “Discrimination, trust, and withholding information from providers: Implications for missing data and inequity,” *SSM—Population Health* (Apr. 7, 2022), <https://www.sciencedirect.com/science/article/pii/S2352827322000714>; See also S.J. Nass et al., “Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research,” Institute of Medicine (US) Committee on Health Research and the Privacy of Health Information: The HIPAA Privacy Rule (2009), <https://www.ncbi.nlm.nih.gov/books/NBK9579/>.
- 441 See Danielle Keats Citron & Daniel J. Solove, “Privacy Harms,” GWU Legal Studies Research Paper No. 2021-11, GWU Law School Public Law Research Paper No. 2021-11, 102 B.U. L. Rev. 793, 830-861 (Feb. 9, 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3782222.
- 442 See “Reclaiming Tort Law to Protect Reproductive Rights,” *supra* note 152.
- 443 See Div. of Reproductive Health, Nat'l Ctr. for Chronic Disease Prevention and Health Promotion, “Women With Chronic Conditions Struggle to Find Medications After Abortion Laws Limit Access,” Ctrs. for Disease Control and Prevention (Jan. 4, 2023), <https://www.cdc.gov/teenpregnancy/health-care-providers/index.htm>; see also Brittnei Frederiksen et al., “Abortion Bans May Limit Essential Medications for Women with Chronic Conditions,” Kaiser Family Foundation (Nov. 17, 2022), <https://www.kff.org/womens-health-policy/issue-brief/abortion-bans-may-limit-essential-medications-for-women-with-chronic-conditions/>.
- 444 See Lynn M. Yee et al., “Association of Health Literacy Among Nulliparous Individuals and Maternal and Neonatal Outcomes,” *JAMA Network Open* (Sept. 1, 2021), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2783674>.
- 445 See “Texas Maternal Mortality and Morbidity Review Committee and Department of State Health Services Joint Biennial Report 2022,” *supra* note 123.
- 446 See Helen Levy & Alex Janke, “Health Literacy and Access to Care,” *J. of Health Commc'n* (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4924568/>; see also Brief for Zurawski, *Zurawski v. State of Texas* (No.

D-1-GN-23-000968) (W.D. Tex. 2023), <https://reproductiverights.org/wp-content/uploads/2023/03/Zurawski-v-State-of-Texas-Complaint.pdf>.

447 See Brief for Zurawski, at 10, *supra* note 447.

448 Public Law 93-579, 88 Stat. 1896 (Dec. 31, 1974) (codified at 5 U.S.C. 552a).

449 40 FR 28948, 28955 (July 9, 1975).

450 42 U.S.C. 1320d-6(a).

451 A person (including an employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in section 1320d-9(b)(3) of this title) and the individual obtained or disclosed such information without authorization. *Id.*

452 $696,898 = 774,331 \times .90$.

453 See U.S. Small Business Administration, Table of Small Business Size Standards (Mar. 17, 2023), https://www.sba.gov/sites/sbagov/files/2023-06/TableofSizeStandards_EffectiveMarch172023-2_.pdf.

454 *Id.*

455 Kaiser Family Foundation, “Market Share and Enrollment of Largest Three Insurers—Large Group Market” (2019), <https://www.kff.org/other/state-indicator/market-share-and-enrollment-of-largest-three-insurers-large-group-market/?currentTimeframe=0&sortModel=#`colId`:`Location`,`sort`:`asc`>.

456 This figure represents annualized costs discounted at a 3% rate.

457 42 U.S.C. 1320d-7(a)(1).

458 42 U.S.C. 1320d-7(a)(2)(A).

459 45 CFR 160.201 through 160.205.

460 Public Law 105-277, 112 Stat. 2681 (Oct. 21, 1998).

461 Public Law 104-13, 109 Stat. 163 (May 22, 1995).

462 This includes an increase of 416 burden hours and \$36,442 in costs added to the existing information collection for requesting exemption determinations under 45 CFR 160.204.

463 See Off. for Civil Rights, “Annual Report to Congress on Breaches of Unsecured Protected Health Information,” U.S. Dep’t of Health and Human Servs. (2022), <https://www.hhs.gov/hipaa/for-professionals/breach-notification/reports-congress/index.html>.

Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations

OH Const. Art. XVIII, Refs & Annos
[Currentness](#)

Const. Art. XVIII, Refs & Annos, OH CONST Art. XVIII, Refs & Annos
Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 1

O Const XVIII Sec. 1 Classification of cities and villages; transition

[Currentness](#)

Municipal corporations are hereby classified into cities and villages. All such corporations having a population of five thousand or over shall be cities; all others shall be villages. The method of transition from one class to the other shall be regulated by law.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

[Notes of Decisions \(26\)](#)

Const. Art. XVIII, § 1, OH CONST Art. XVIII, § 1

Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 2

O Const XVIII Sec. 2 General laws for incorporation and government of municipalities; additional laws; referendum

[Currentness](#)

General laws shall be passed to provide for the incorporation and government of cities and villages; and additional laws may also be passed for the government of municipalities adopting the same; but no such additional law shall become operative in any municipality until it shall have been submitted to the electors thereof, and affirmed by a majority of those voting thereon, under regulations to be established by law.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

[Notes of Decisions \(25\)](#)

Const. Art. XVIII, § 2, OH CONST Art. XVIII, § 2

Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 3

O Const XVIII Sec. 3 Municipal powers of local self-government

[Currentness](#)

Subject to the requirements of [Section 1 of Article V of this constitution](#), municipalities shall have authority to exercise all powers of local self-government and to adopt and enforce within their limits such local police, sanitary and other similar regulations, as are not in conflict with general laws.

CREDIT(S)

(2022 HJR 4, am. eff. 11-8-22; 1912 constitutional convention, adopted eff. 11-15-12)

[Notes of Decisions \(1557\)](#)

Const. Art. XVIII, § 3, OH CONST Art. XVIII, § 3

Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 4

O Const XVIII Sec. 4 Municipality may acquire public utility or contract for utility services

[Currentness](#)

Any municipality may acquire, construct, own, lease and operate within or without its corporate limits, any public utility the products or service of which is or is to be supplied to the municipality or its inhabitants, and may contract with others for any such product or service. The acquisition of any such public utility may be by condemnation or otherwise, and a municipality may acquire thereby the use of, or full title to, the property and franchise of any company or person supplying to the municipality or its inhabitants the service or produce of any such utility.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

[Notes of Decisions \(246\)](#)

Const. Art. XVIII, § 4, OH CONST Art. XVIII, § 4

Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 5

O Const XVIII Sec. 5 Referendum on acquiring or operating municipal utility

[Currentness](#)

Any municipality proceeding to acquire, construct, own, lease or operate a public utility, or to contract with any person or company therefor, shall act by ordinance and no such ordinance shall take effect until after thirty days from its passage. If within said thirty days a petition signed by ten per centum of the electors of the municipality shall be filed with the executive authority thereof demanding a referendum on such ordinance it shall not take effect until submitted to the electors and approved by a majority of those voting thereon. The submission of any such question shall be governed by all the provisions of section 8 of this article as to the submission of the question of choosing a charter commission.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

[Notes of Decisions \(49\)](#)

Const. Art. XVIII, § 5, OH CONST Art. XVIII, § 5

Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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KeyCite Yellow Flag - Negative Treatment

Unconstitutional or Preempted Limitation Recognized by [Duke Energy Ohio, Inc. v. Hamilton](#), Ohio App. 12 Dist., Oct. 25, 2021

[Baldwin's Ohio Revised Code Annotated](#)

[Constitution of the State of Ohio](#)

[Article XVIII. Municipal Corporations \(Refs & Annos\)](#)

OH Const. Art. XVIII, § 6

O Const XVIII Sec. 6 Sale of surplus product of municipal utility; limitation

[Currentness](#)

Any municipality, owning or operating a public utility for the purpose of supplying the service or product thereof to the municipality or its inhabitants, may also sell and deliver to others any transportation service of such utility and the surplus product of any other utility in an amount not exceeding in either case fifty per cent of the total service or product supplied by such utility within the municipality, provided that such fifty per cent limitation shall not apply to the sale of water or sewage services.

CREDIT(S)

(128 v 1355, am. eff. 11-3-59; 1912 constitutional convention, adopted eff. 11-15-12)

[Notes of Decisions \(60\)](#)

Const. Art. XVIII, § 6, OH CONST Art. XVIII, § 6

Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 7

O Const XVIII Sec. 7 Municipal charter

[Currentness](#)

Any municipality may frame and adopt or amend a charter for its government and may, subject to the provisions of section 3 of this article, exercise thereunder all powers of local self-government.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

[Notes of Decisions \(348\)](#)

Const. Art. XVIII, § 7, OH CONST Art. XVIII, § 7

Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 8

O Const XVIII Sec. 8 Referenda on whether to frame charter and on adoption of proposed charter

[Currentness](#)

The legislative authority of any city or village may by a two-thirds vote of its members, and upon petition of ten per centum of the electors shall forthwith, provide by ordinance for the submission to the electors, of the question, "Shall a commission be chosen to frame a charter." The ordinance providing for the submission of such question shall require that it be submitted to the electors at the next regular municipal election if one shall occur not less than sixty nor more than one hundred and twenty days after its passage; otherwise it shall provide for the submission of the question at a special election to be called and held within the time aforesaid. The ballot containing such question shall bear no party designation, and provision shall be made thereon for the election from the municipality at large of fifteen electors who shall constitute a commission to frame a charter; provided that a majority of the electors voting on such question shall have voted in the affirmative. Any charter so framed shall be submitted to the electors of the municipality at an election to be held at a time fixed by the charter commission and within one year from the date of its election, provision for which shall be made by the legislative authority of the municipality in so far as not prescribed by general law. Not less than thirty days prior to such election the clerk of the municipality shall mail a copy of the proposed charter to each elector whose name appears upon the poll or registration books of the last regular or general election held therein. If such proposed charter is approved by a majority of the electors voting thereon it shall become the charter of such municipality at the time fixed therein.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

[Notes of Decisions \(96\)](#)

Const. Art. XVIII, § 8, OH CONST Art. XVIII, § 8
Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 9

O Const XVIII Sec. 9 Amendment of charter; referendum

[Currentness](#)

Amendments to any charter framed and adopted as herein provided may be submitted to the electors of a municipality by a two-thirds vote of the legislative authority thereof, and upon petitions signed by ten per centum of the electors of the municipality setting forth any such proposed amendment, shall be submitted by such legislative authority. The submission of proposed amendments to the electors shall be governed by the requirements of section 8 as to the submission of the question of choosing a charter commission; and copies of proposed amendments may be mailed to the electors as hereinbefore provided for copies of a proposed charter, or, pursuant to laws passed by the General Assembly, notice of proposed amendments may be given by newspaper advertising. If any such amendment is approved by a majority of the electors voting thereon, it shall become a part of the charter of the municipality. A copy of said charter or any amendment thereto shall be certified to the secretary of state, within thirty days after adoption by a referendum vote.

CREDIT(S)

(1970 SJR 31, am. eff. 1-1-71; 1912 constitutional convention, adopted eff. 11-15-12)

[Notes of Decisions \(77\)](#)

Const. Art. XVIII, § 9, OH CONST Art. XVIII, § 9

Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 10

O Const XVIII Sec. 10 Acquiring property exceeding public needs

[Currentness](#)

A municipality appropriating or otherwise acquiring property for public use may in furtherance of such public use appropriate or acquire an excess over that actually to be occupied by the improvement, and may sell such excess with such restrictions as shall be appropriate to preserve the improvement made. Bonds may be issued to supply the funds in whole or in part to pay for the excess property so appropriated or otherwise acquired, but said bonds shall be a lien only against the property so acquired for the improvement and excess, and they shall not be a liability of the municipality nor be included in any limitation of the bonded indebtedness of such municipality prescribed by law.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

[Notes of Decisions \(24\)](#)

Const. Art. XVIII, § 10, OH CONST Art. XVIII, § 10

Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 11

O Const XVIII Sec. 11 Assessment of benefitted property to pay for improvements

Currentness

Any municipality appropriating private property for a public improvement may provide money therefor in part by assessments upon benefitted property not in excess of the special benefits conferred upon such property by the improvements. Said assessments, however, upon all the abutting, adjacent, and other property in the district benefitted, shall in no case be levied for more than fifty per centum of the cost of such appropriation.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (3)

Const. Art. XVIII, § 11, OH CONST Art. XVIII, § 11

Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 12

O Const XVIII Sec. 12 Mortgage bonds to finance municipal utilities

[Currentness](#)

Any municipality which acquires, constructs or extends any public utility and desires to raise money for such purposes may issue mortgage bonds therefor beyond the general limit of bonded indebtedness prescribed by law; provided that such mortgage bonds issued beyond the general limit of bonded indebtedness prescribed by law shall not impose any liability upon such municipality but shall be secured only upon the property and revenues of such public utility, including a franchise stating the terms upon which, in case of foreclosure, the purchaser may operate the same, which franchise shall in no case extend for a longer period than twenty years from the date of the sale of such utility and franchise on foreclosure.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

[Notes of Decisions \(20\)](#)

Const. Art. XVIII, § 12, OH CONST Art. XVIII, § 12

Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 13

O Const XVIII Sec. 13 Laws limiting municipal power to tax and incur debts; financial reports; audits

[Currentness](#)

Laws may be passed to limit the power of municipalities to levy taxes and incur debts for local purposes, and may require reports from municipalities as to their financial condition and transactions, in such form as may be provided by law, and may provide for the examination of the vouchers, books and accounts of all municipal authorities, or of public undertakings conducted by such authorities.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

[Notes of Decisions \(85\)](#)

Const. Art. XVIII, § 13, OH CONST Art. XVIII, § 13

Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 14

O Const XVIII Sec. 14 Municipal elections

[Currentness](#)

All elections and submissions of questions provided for in this article shall be conducted by the election authorities prescribed by general law. The percentage of electors required to sign any petition provided for herein shall be based upon the total vote cast at the last preceding general municipal election.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

[Notes of Decisions \(7\)](#)

Const. Art. XVIII, § 14, OH CONST Art. XVIII, § 14

Current through Files 1 to 59, 61, and 63 of the 135th General Assembly (2023-2024).

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West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law

W.S.A. Ch. 66, Refs & Annos
[Currentness](#)

Editors' Notes

REORGANIZATION OF CHAPTER

<St.1997, Chapter 66, General Municipality Law, was reorganized by 1999 Act 150, effective Jan. 1, 2001. Section renumbering lines and repeal notes provide, where appropriate, the disposition of subject matter of the chapter's sections prior to the reorganization.>

W. S. A. Ch. 66, Refs & Annos, WI ST Ch. 66, Refs & Annos
Current through 2023 Act 272, published April 10, 2024.

End of Document

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West's Wisconsin Statutes Annotated

Municipalities (Ch. 59 to 68)

Chapter 66. General Municipality Law (Refs & Annos)

Subchapter II. Incorporation; Municipal Boundaries

W.S.A. 66.0201

66.0201. Incorporation of villages and cities; purpose and definitions

Currentness

(1) Purpose. It is the policy of this state that the development of territory from town to incorporated status proceed in an orderly and uniform manner and that toward this end each proposed incorporation of territory as a village or city be reviewed as provided in ss. 66.0201 to [66.0213](#) to assure compliance with certain minimum standards which take into account the needs of both urban and rural areas.

(2) Definitions. In ss. 66.0201 to [66.0213](#), unless the context requires otherwise:

(am) “Board” means the incorporation review board.

(ar) “Department” means the department of administration.

(bm) “Isolated municipality” means any existing or proposed village or city entirely outside any metropolitan community at the time of its incorporation.

(c) “Metropolitan community” means the territory consisting of any city having a population of 25,000 or more, or any 2 incorporated municipalities whose boundaries are within 5 miles of each other whose populations aggregate 25,000, plus all the contiguous area which has a population density of 100 persons or more per square mile, or which the department has determined on the basis of population trends and other pertinent facts will have a minimum density of 100 persons per square mile within 3 years.

(d) “Metropolitan municipality” means any existing or proposed village or city entirely or partly within a metropolitan community.

(dm) “Population” means the population of a local unit as shown by the last federal census or by any subsequent population estimate certified as acceptable by the department.

Credits

<<For credits, see Historical Note field.>>

[Notes of Decisions \(5\)](#)

W. S. A. 66.0201, WI ST 66.0201

Current through 2023 Act 272, published April 10, 2024.

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KeyCite Red Flag - Severe Negative Treatment

Unconstitutional or Preempted Held Unconstitutional by [State ex rel. Kuehne v. Burdette](#), Wis.App., Apr. 14, 2009

[West's Wisconsin Statutes Annotated](#)

[Municipalities \(Ch. 59 to 68\)](#)

[Chapter 66. General Municipality Law \(Refs & Annos\)](#)

[Subchapter II. Incorporation; Municipal Boundaries](#)

W.S.A. 66.0203

66.0203. Procedure for incorporation of villages and cities

[Currentness](#)

(1) Notice of intention. At least 10 days and not more than 20 days before the circulation of an incorporation petition, a notice setting forth that the petition is to be circulated and including an accurate description of the territory involved shall be published within the county in which the territory is located as a class 1 notice, under ch. 985.

(2) Petition. (a) The petition for incorporation of a village or city shall be in writing signed by 50 or more persons who are both electors and freeholders in the territory to be incorporated if the population of the proposed village or city includes 300 or more persons; otherwise by 25 or more persons who are both electors and freeholders in the territory to be incorporated.

(b) The petition shall be addressed to and filed with the circuit court of a county in which all or a major part of the territory to be incorporated is located. The incorporation petition is void unless filed within 6 months of the date of publication of the notice of intention to circulate.

(c) The petition shall designate a representative of the petitioners, and an alternate, who shall be an elector or freeholder in the territory, and state that person's address; describe the territory to be incorporated with sufficient accuracy to determine its location and have attached to the petition a scale map reasonably showing the boundaries of the territory; specify the current resident population of the territory by number in accordance with the definition given in [s. 66.0201\(2\)\(dm\)](#); set forth facts substantially establishing the required standards for incorporation; and request the circuit court to order a referendum and to certify the incorporation of the village or city when it is found that all requirements have been met.

(e) No person who has signed a petition may withdraw his or her name from the petition. No additional signatures may be added after a petition is filed.

(f) The circulation of the petition shall commence not less than 10 days nor more than 20 days after the date of publication of the notice of intention to circulate.

(3) Hearing; costs. (a) Upon the filing of the petition the circuit court shall by order fix a time and place for a hearing giving preference to the hearing over other matters on the court calendar.

(b) The court may by order allow costs and disbursements as provided for actions in circuit court in any proceeding under this subsection.

(c) The court may, upon notice to all parties who have appeared in the hearing and after a hearing on the issue of bond, order the petitioners or any of the opponents to post bond in an amount that it considers sufficient to cover disbursements.

(4) Notice. (a) Notice of the filing of the petition and of the date of the hearing on the petition before the circuit court shall be published in the territory to be incorporated, as a class 2 notice, under ch. 985, and given by certified or registered mail to the clerk of each town in which the territory is located and to the clerk of each metropolitan municipality of the metropolitan community in which the territory is located. The mailing shall be not less than 10 days before the time set for the hearing.

(b) The notice shall contain:

1. A description of the territory sufficiently accurate to determine its location and a statement that a scale map reasonably showing the boundaries of the territory is on file with the circuit court.
2. The name of each town in which the territory is located.
3. The name and post-office address of the representative of the petitioners.

(4m) Incorporations involving portions of 2 towns. If the territory designated in the petition is comprised of portions of only 2 towns, the territory may not be incorporated unless the town board of each town adopts a resolution approving the incorporation.

(5) Parties. Any governmental unit entitled to notice pursuant to sub. (4), any school district which lies at least partly in the territory or any other person found by the court to be a party in interest may become a party to the proceeding prior to the time set for the hearing.

(6) Annexation resolution. Any municipality whose boundaries are contiguous to the territory may also file with the circuit court a certified copy of a resolution adopted by a two-thirds vote of the elected members of the governing body indicating a willingness to annex the territory designated in the incorporation petition. The resolution shall be filed at or prior to the hearing on the incorporation petition, or any adjournment granted for this purpose by the court.

(7) Action. (a) No action to contest the validity of an incorporation on any grounds, whether procedural or jurisdictional, may be commenced after 60 days from the date of issuance of the certificate of incorporation by the secretary of administration.

(b) An action contesting an incorporation shall be given preference in the circuit court.

(8) Function of the circuit court. (a) After the filing of the petition and proof of notice, the circuit court shall conduct a hearing at the time and place specified in the notice, or at a time and place to which the hearing is duly adjourned.

(b) On the basis of the hearing the circuit court shall find if the standards under [s. 66.0205](#) are met. If the court finds that the standards are not met, the court shall dismiss the petition. Subject to par. (c), if the court finds that the standards are met the court shall refer the petition to the board. Upon payment of any fee imposed under [s. 16.53\(14\)](#), the board shall determine whether the standards under [s. 66.0207](#) are met.

(c)1. The court shall determine whether an annexation proceeding that affects any territory included in the incorporation petition has been initiated under [s. 66.0217](#), [66.0219](#), or [66.0223](#). A court shall consider an annexation proceeding under [s. 66.0223](#) to have been initiated upon the posting of a meeting notice by a city or village that states that the city or village is considering enacting an ordinance under [s. 66.0223](#).

2. If the court determines that an annexation proceeding described under subd. 1. was initiated before the publication of the notice under sub. (1), the court shall refer the petition to the board when the annexation proceeding is final. If the annexation is determined to be valid, the court shall exclude the annexed territory from the territory proposed to be incorporated when it refers the petition to the board.

3. If the court determines that an annexation proceeding described under subd. 1. was initiated after, and within 30 days after, the publication of the notice under sub. (1), the annexation may not proceed until the validity of the incorporation has been determined. If the incorporation is determined to be valid and complete, the annexation is void. If the incorporation is determined to be invalid, the annexation may proceed.

4. If the court determines that an annexation proceeding described under subd. 1. was initiated on the same date as the publication of the notice under sub. (1), the court shall determine which procedure was begun first on that date and that action may proceed and the other action may not proceed unless the first action fails.

5. If the court determines that an annexation proceeding described under subd. 1. was initiated more than 30 days after the publication of the notice under sub. (1), the annexation is void.

(9) Function of the board. (a) Upon receipt of the petition from the circuit court and payment of any fee imposed under [s. 16.53\(14\)](#), the board shall make any necessary investigation to apply the standards under [s. 66.0207](#).

(b) Within 30 days after the receipt by the board of the petition from the circuit court and payment of any fee imposed under [s. 16.53\(14\)](#), whichever is later, any party in interest may request a hearing. Upon receipt of the request, the board shall schedule a hearing at a place in or convenient to the territory sought to be incorporated.

(c) Notice of the hearing shall be given in the territory to be incorporated by publishing a class 2 notice, under ch. 985, and by mailing the notice to the designated representative of the petitioners or any 5 petitioners and to all town and municipal clerks entitled to receive mailed notice of the petition under sub. (4).

(d) Subject to par. (dm), unless the court sets a different time limit, the board shall prepare its findings and determination, citing the supporting evidence, within 180 days after receipt of the referral from the court and payment of any fee imposed under [s. 16.53\(14\)](#), whichever is later. The findings and determination shall be forwarded by the board to the circuit court. Copies of the

findings and determination shall be sent by certified or registered mail to the designated representative of the petitioners, and to all town and municipal clerks entitled to receive mailed notice of the petition under sub. (4).

(dm) The time period specified or set by the court under par. (d) shall be stayed for a reasonable period of time to allow for alternative dispute resolution of any disagreements between interested parties that result from the filing of an incorporation petition if all interested parties agree to this stay and provide written notice of their agreement to the board and to the circuit court.

(e) The determination of the board made in accordance with the standards under ss. 66.0205, 66.0207 and 66.0217(6)(c) shall be one of the following:

1. The petition as submitted is dismissed.

2. The petition as submitted is granted.

3. The petition as submitted is dismissed with a recommendation that a new petition be submitted to include more or less territory as specified in the department's findings and determination.

(f)1. If the board determines that the petition shall be dismissed under par. (e)1., the circuit court shall issue an order dismissing the petition. Except as provided in subd. 2., if the board grants the petition, the circuit court shall order an incorporation referendum as provided in s. 66.0211.

2. If sub. (4m) applies, the court shall dismiss the petition if the court does not find that the resolutions required under sub. (4m) have been adopted. Paragraph (g) does not apply to this subdivision.

(g) The findings of both the court and the board shall be based upon facts as they existed at the time of the filing of the petition.

(h) Except for an incorporation petition which describes the territory recommended by the board under sub. (9)(e)3., no petition for the incorporation of the same or substantially the same territory may be entertained for one year following the date of dismissal under par. (f) of the petition or the date of any election at which incorporation was rejected by the electors.

(i) If the board fails to make a determination within the time limit under par. (d), the board shall refund the fees imposed by the board under s. 16.53(14) and shall then make a determination as quickly as possible.

(10) Certain towns may become a city or village. A town that is adjacent to a village that contains an electronics and information technology manufacturing zone that is designated under s. 238.396(1m) may become a city or village if the town holds, and approves, an incorporation referendum as described in s. 66.0211(3). None of the other procedures contained in ss. 66.0201 to 66.0213 need to be fulfilled, and no approval by the board under s. 66.0207 is necessary for the town to become a city or village.

Credits

<<For credits, see Historical Note field.>>

[Notes of Decisions \(40\)](#)

W. S. A. 66.0203, WI ST 66.0203

Current through 2023 Act 272, published April 10, 2024.

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KeyCite Yellow Flag - Negative Treatment

Unconstitutional or Preempted Validity Called into Doubt by [Purl v. United States Department of Health and Human Services](#), N.D.Tex., Dec. 22, 2024



KeyCite Yellow Flag - Negative Treatment

Proposed Regulation

[Code of Federal Regulations](#)

[Title 45. Public Welfare](#)

[Subtitle A. Department of Health and Human Services \(Refs & Annos\)](#)

[Subchapter C. Administrative Data Standards and Related Requirements \(Refs & Annos\)](#)

[Part 160. General Administrative Requirements \(Refs & Annos\)](#)

[Subpart A. General Provisions](#)

45 C.F.R. § 160.103

§ 160.103 Definitions.

[Currentness](#)

Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act.

Administrative simplification provision means any requirement or prohibition established by:

- (1) [42 U.S.C. 1320d–1320d–4](#), [1320d–7](#), [1320d–8](#), and [1320d–9](#);
- (2) [Section 264 of Pub.L. 104–191](#);
- (3) Sections 13400–13424 of [Public Law 111–5](#); or
- (4) This subchapter.

ALJ means Administrative Law Judge.

ANSI stands for the American National Standards Institute.

Business associate:

- (1) Except as provided in paragraph (4) of this definition, business associate means, with respect to a covered entity, a person who:
 - (i) On behalf of such covered entity or of an organized health care arrangement (as defined in this section) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this subchapter, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at [42 CFR 3.20](#), billing, benefit management, practice management, and repricing; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of protected health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity may be a business associate of another covered entity.

(3) Business associate includes:

(i) A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires access on a routine basis to such protected health information.

(ii) A person that offers a personal health record to one or more individuals on behalf of a covered entity.

(iii) A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.

(4) Business associate does not include:

(i) A health care provider, with respect to disclosures by a covered entity to the health care provider concerning the treatment of the individual.

(ii) A plan sponsor, with respect to disclosures by a group health plan (or by a health insurance issuer or HMO with respect to a group health plan) to the plan sponsor, to the extent that the requirements of § 164.504(f) of this subchapter apply and are met.

(iii) A government agency, with respect to determining eligibility for, or enrollment in, a government health plan that provides public benefits and is administered by another government agency, or collecting protected health information for such purposes, to the extent such activities are authorized by law.

(iv) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement by virtue of such activities or services.

Civil money penalty or penalty means the amount determined under § 160.404 of this part and includes the plural of these terms.

CMS stands for Centers for Medicare & Medicaid Services within the Department of Health and Human Services.

Compliance date means the date by which a covered entity or business associate must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

Covered entity means:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

Disclosure means the release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information.

EIN stands for the employer identification number assigned by the Internal Revenue Service, U.S. Department of the Treasury. The EIN is the taxpayer identifying number of an individual or other entity (whether or not an employer) assigned under one of the following:

- (1) [26 U.S.C. 6011\(b\)](#), which is the portion of the Internal Revenue Code dealing with identifying the taxpayer in tax returns and statements, or corresponding provisions of prior law.
- (2) [26 U.S.C. 6109](#), which is the portion of the Internal Revenue Code dealing with identifying numbers in tax returns, statements, and other required documents.

Electronic media means:

- (1) Electronic storage material on which data is or may be recorded electronically, including, for example, devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card;
- (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the Internet, extranet or intranet, leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media if the information being exchanged did not exist in electronic form immediately before the transmission.

Electronic protected health information means information that comes within paragraphs (1)(i) or (1)(ii) of the definition of protected health information as specified in this section.

Employer is defined as it is in [26 U.S.C. 3401\(d\)](#).

Family member means, with respect to an individual:

- (1) A dependent (as such term is defined in [45 CFR 144.103](#)), of the individual; or
- (2) Any other person who is a first-degree, second-degree, third-degree, or fourth-degree relative of the individual or of a dependent of the individual. Relatives by affinity (such as by marriage or adoption) are treated the same as relatives by consanguinity (that is, relatives who share a common biological ancestor). In determining the degree of the relationship, relatives by less than full consanguinity (such as half-siblings, who share only one parent) are treated the same as relatives by full consanguinity (such as siblings who share both parents).
 - (i) First-degree relatives include parents, spouses, siblings, and children.
 - (ii) Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces.
 - (iii) Third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.

(iv) Fourth-degree relatives include great-great grandparents, great-great grandchildren, and children of first cousins.

Genetic information means:

(1) Subject to paragraphs (2) and (3) of this definition, with respect to an individual, information about:

(i) The individual's genetic tests;

(ii) The genetic tests of family members of the individual;

(iii) The manifestation of a disease or disorder in family members of such individual; or

(iv) Any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by the individual or any family member of the individual.

(2) Any reference in this subchapter to genetic information concerning an individual or family member of an individual shall include the genetic information of:

(i) A fetus carried by the individual or family member who is a pregnant woman; and

(ii) Any embryo legally held by an individual or family member utilizing an assisted reproductive technology.

(3) Genetic information excludes information about the sex or age of any individual.

Genetic services means:

(1) A genetic test;

(2) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(3) Genetic education.

Genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. Genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition.

Group health plan (also see definition of health plan in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), [29 U.S.C. 1002\(1\)](#)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), [42 U.S.C. 300gg-91\(a\)\(2\)](#)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

(1) Has 50 or more participants (as defined in [section 3\(7\)](#) of ERISA, [29 U.S.C. 1002\(7\)](#)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

HHS stands for the Department of Health and Human Services.

Health care means care, services, or supplies related to the health of an individual. Health care includes, but is not limited to, the following:

- (1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and
- (2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

Health care clearinghouse means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and “value-added” networks and switches, that does either of the following functions:

- (1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.
- (2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Health care provider means a provider of services (as defined in section 1861(u) of the Act, [42 U.S.C. 1395x\(u\)](#)), a provider of medical or health services (as defined in section 1861(s) of the Act, [42 U.S.C. 1395x\(s\)](#)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health information means any information, including genetic information, whether oral or recorded in any form or medium, that:

- (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
- (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health insurance issuer (as defined in section 2791(b)(2) of the PHS Act, [42 U.S.C. 300gg–91\(b\)\(2\)](#) and used in the definition of health plan in this section) means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Health maintenance organization (HMO) (as defined in section 2791(b)(3) of the PHS Act, [42 U.S.C. 300gg–91\(b\)\(3\)](#) and used in the definition of health plan in this section) means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, [42 U.S.C. 300gg–91\(a\)\(2\)](#)).

- (1) Health plan includes the following, singly or in combination:
 - (i) A group health plan, as defined in this section.
 - (ii) A health insurance issuer, as defined in this section.

- (iii) An HMO, as defined in this section.
 - (iv) Part A or Part B of the Medicare program under title XVIII of the Act.
 - (v) The Medicaid program under title XIX of the Act, [42 U.S.C. 1396, et seq.](#)
 - (vi) The Voluntary Prescription Drug Benefit Program under Part D of title XVIII of the Act, [42 U.S.C. 1395w–101](#) through [1395w–152](#).
 - (vii) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, [42 U.S.C. 1395ss\(g\)\(1\)](#)).
 - (viii) An issuer of a long-term care policy, excluding a nursing home fixed indemnity policy.
 - (ix) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.
 - (x) The health care program for uniformed services under title 10 of the United States Code.
 - (xi) The veterans health care program under 38 U.S.C. chapter 17.
 - (xii) The Indian Health Service program under the Indian Health Care Improvement Act, [25 U.S.C. 1601, et seq.](#)
 - (xiii) The Federal Employees Health Benefits Program under [5 U.S.C. 8902, et seq.](#)
 - (xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, [42 U.S.C. 1397, et seq.](#)
 - (xv) The Medicare Advantage program under Part C of title XVIII of the Act, [42 U.S.C. 1395w–21](#) through [1395w–28](#).
 - (xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.
 - (xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, [42 U.S.C. 300gg–91\(a\)\(2\)](#)).
- (2) Health plan excludes:
- (i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, [42 U.S.C. 300gg–91\(c\)\(1\)](#); and
 - (ii) A government-funded program (other than one listed in paragraph (1)(i)–(xvi) of this definition):
 - (A) Whose principal purpose is other than providing, or paying the cost of, health care; or
 - (B) Whose principal activity is:
- (1) The direct provision of health care to persons; or

(2) The making of grants to fund the direct provision of health care to persons.

Implementation specification means specific requirements or instructions for implementing a standard.

Individual means the person who is the subject of protected health information.

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

- (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
- (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
- (i) That identifies the individual; or
- (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Manifestation or manifested means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this subchapter, a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information.

Modify or modification refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification.

Organized health care arrangement means:

- (1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;
- (2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities:
 - (i) Hold themselves out to the public as participating in a joint arrangement; and
 - (ii) Participate in joint activities that include at least one of the following:
 - (A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;
 - (B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or
 - (C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

Person means a natural person (meaning a human being who is born alive), trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Protected health information means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in electronic media; or

(iii) Transmitted or maintained in any other form or medium.

(2) Protected health information excludes individually identifiable health information:

(i) In education records covered by the Family Educational Rights and Privacy Act, as amended, [20 U.S.C. 1232g](#);

(ii) In records described at [20 U.S.C. 1232g\(a\)\(4\)\(B\)\(iv\)](#);

(iii) In employment records held by a covered entity in its role as employer; and

(iv) Regarding a person who has been deceased for more than 50 years.

Public health, as used in the terms “public health surveillance,” “public health investigation,” and “public health intervention,” means population-level activities to prevent disease in and promote the health of populations. Such activities include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information. But such activities do not include those with any of the following purposes:

(1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating health care.

(2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care.

(3) To identify any person for any of the activities described at paragraphs (1) or (2) of this definition.

Reproductive health care means health care, as defined in this section, that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes. This definition shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care.

Respondent means a covered entity or business associate upon which the Secretary has imposed, or proposes to impose, a civil money penalty.

Secretary means the Secretary of Health and Human Services or any other officer or employee of HHS to whom the authority involved has been delegated.

Small health plan means a health plan with annual receipts of \$5 million or less.

Standard means a rule, condition, or requirement:

(1) Describing the following information for products, systems, services, or practices:

(i) Classification of components;

(ii) Specification of materials, performance, or operations; or

(iii) Delineation of procedures; or

(2) With respect to the privacy of protected health information.

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

State refers to one of the following:

(1) For a health plan established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, State means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Subcontractor means a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

Transaction means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions:

(1) Health care claims or equivalent encounter information.

(2) Health care payment and remittance advice.

(3) Coordination of benefits.

- (4) Health care claim status.
- (5) Enrollment and disenrollment in a health plan.
- (6) Eligibility for a health plan.
- (7) Health plan premium payments.
- (8) Referral certification and authorization.
- (9) First report of injury.
- (10) Health claims attachments.
- (11) Health care electronic funds transfers (EFT) and remittance advice.
- (12) Other transactions that the Secretary may prescribe by regulation.

Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

Violation or violate means, as the context may require, failure to comply with an administrative simplification provision.

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate.

Credits

[[67 FR 38019](#), May 31, 2002; [67 FR 53266](#), Aug. 14, 2002; [68 FR 8374](#), Feb. 20, 2003; [71 FR 8424](#), Feb. 16, 2006; [76 FR 40495](#), July 8, 2011; [77 FR 1589](#), Jan. 10, 2012; [78 FR 5687](#), Jan. 25, 2013; [79 FR 36432](#), June 27, 2014; [89 FR 33062](#), April 26, 2024]

SOURCE: [65 FR 50365](#), Aug. 17, 2000; [65 FR 82798](#), Dec. 28, 2000; [66 FR 12434](#), Feb. 26, 2001; [68 FR 18901](#), April 17, 2003; [71 FR 8424](#), Feb. 16, 2006; [74 FR 42767](#), Aug. 24, 2009; [74 FR 56130](#), Oct. 30, 2009; [76 FR 40495](#), July 8, 2011; [78 FR 5687](#), Jan. 25, 2013, unless otherwise noted.

AUTHORITY: [42 U.S.C. 1302\(a\)](#); [42 U.S.C. 1320d–1320d–9](#); sec. 264, [Pub.L. 104–191](#), [110 Stat. 2033–2034](#) ([42 U.S.C. 1320d–2 \(note\)](#)); [5 U.S.C. 552](#); secs. 13400–13424, [Pub.L. 111–5](#), [123 Stat. 258–279](#); and sec. 1104 of [Pub.L. 111–148](#), [124 Stat. 146–154](#).

Notes of Decisions (33)

Current through February 7, 2025, 90 FR 9128. Some sections may be more current. See credits for details.



KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 42. The Public Health and Welfare
Chapter 7. Social Security (Refs & Annos)
Subchapter XI. General Provisions, Peer Review, and Administrative Simplification (Refs & Annos)
Part C. Administrative Simplification

42 U.S.C.A. § 1320d-5

§ 1320d-5. General penalty for failure to comply with requirements and standards

Currentness

(a) General penalty

(1) In general

Except as provided in subsection (b), the Secretary shall impose on any person who violates a provision of this part--

(A) in the case of a violation of such provision in which it is established that the person did not know (and by exercising reasonable diligence would not have known) that such person violated such provision, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(A) but not to exceed the amount described in paragraph (3)(D);

(B) in the case of a violation of such provision in which it is established that the violation was due to reasonable cause and not to willful neglect, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(B) but not to exceed the amount described in paragraph (3)(D); and

(C) in the case of a violation of such provision in which it is established that the violation was due to willful neglect--

(i) if the violation is corrected as described in subsection (b)(3)(A),¹ a penalty in an amount that is at least the amount described in paragraph (3)(C) but not to exceed the amount described in paragraph (3)(D); and

(ii) if the violation is not corrected as described in such subsection, a penalty in an amount that is at least the amount described in paragraph (3)(D).

In determining the amount of a penalty under this section for a violation, the Secretary shall base such determination on the nature and extent of the violation and the nature and extent of the harm resulting from such violation.

(2) Procedures

The provisions of [section 1320a-7a](#) of this title (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such [section 1320a-7a](#) of this title.

(3) Tiers of penalties described

For purposes of paragraph (1), with respect to a violation by a person of a provision of this part--

(A) the amount described in this subparagraph is \$100 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000;

(B) the amount described in this subparagraph is \$1,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed \$100,000;

(C) the amount described in this subparagraph is \$10,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed \$250,000; and

(D) the amount described in this subparagraph is \$50,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed \$1,500,000.

(b) Limitations

(1) Offenses otherwise punishable

No penalty may be imposed under subsection (a) and no damages obtained under subsection (d) with respect to an act if a penalty has been imposed under [section 1320d-6](#) of this title with respect to such act.

(2) Failures due to reasonable cause

(A) In general

Except as provided in subparagraph (B) or subsection (a)(1)(C), no penalty may be imposed under subsection (a) and no damages obtained under subsection (d) if the failure to comply is corrected during the 30-day period beginning on the first date the person liable for the penalty or damages knew, or by exercising reasonable diligence would have known, that the failure to comply occurred.

(B) Extension of period

(i) No penalty

With respect to the imposition of a penalty by the Secretary under subsection (a), the period referred to in subparagraph (A) may be extended as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

(ii) Assistance

If the Secretary determines that a person failed to comply because the person was unable to comply, the Secretary may provide technical assistance to the person during the period described in subparagraph (A). Such assistance shall be provided in any manner determined appropriate by the Secretary.

(3) Reduction

In the case of a failure to comply which is due to reasonable cause and not to willful neglect, any penalty under subsection (a) and any damages under subsection (d) that is ² not entirely waived under paragraph (3) ³ may be waived to the extent that the payment of such penalty ⁴ would be excessive relative to the compliance failure involved.

(c) Noncompliance due to willful neglect

(1) In general

A violation of a provision of this part due to willful neglect is a violation for which the Secretary is required to impose a penalty under subsection (a)(1).

(2) Required investigation

For purposes of paragraph (1), the Secretary shall formally investigate any complaint of a violation of a provision of this part if a preliminary investigation of the facts of the complaint indicate such a possible violation due to willful neglect.

(d) Enforcement by State attorneys general

(1) Civil action

Except as provided in subsection (b), in any case in which the attorney general of a State has reason to believe that an interest of one or more of the residents of that State has been or is threatened or adversely affected by any person who violates a provision of this part, the attorney general of the State, as parens patriae, may bring a civil action on behalf of such residents of the State in a district court of the United States of appropriate jurisdiction--

(A) to enjoin further such violation by the defendant; or

(B) to obtain damages on behalf of such residents of the State, in an amount equal to the amount determined under paragraph (2).

(2) Statutory damages

(A) In general

For purposes of paragraph (1)(B), the amount determined under this paragraph is the amount calculated by multiplying the number of violations by up to \$100. For purposes of the preceding sentence, in the case of a continuing violation, the number of violations shall be determined consistent with the HIPAA privacy regulations (as defined in [section 1320d-9\(b\)](#) (3) of this title) for violations of subsection (a).

(B) Limitation

The total amount of damages imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000.

(C) Reduction of damages

In assessing damages under subparagraph (A), the court may consider the factors the Secretary may consider in determining the amount of a civil money penalty under subsection (a) under the HIPAA privacy regulations.

(3) Attorney fees

In the case of any successful action under paragraph (1), the court, in its discretion, may award the costs of the action and reasonable attorney fees to the State.

(4) Notice to Secretary

The State shall serve prior written notice of any action under paragraph (1) upon the Secretary and provide the Secretary with a copy of its complaint, except in any case in which such prior notice is not feasible, in which case the State shall serve such notice immediately upon instituting such action. The Secretary shall have the right--

(A) to intervene in the action;

(B) upon so intervening, to be heard on all matters arising therein; and

(C) to file petitions for appeal.

(5) Construction

For purposes of bringing any civil action under paragraph (1), nothing in this section shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State.

(6) Venue; service of process

(A) Venue

Any action brought under paragraph (1) may be brought in the district court of the United States that meets applicable requirements relating to venue under [section 1391 of Title 28](#).

(B) Service of process

In an action brought under paragraph (1), process may be served in any district in which the defendant--

(i) is an inhabitant; or

(ii) maintains a physical place of business.

(7) Limitation on State action while Federal action is pending

If the Secretary has instituted an action against a person under subsection (a) with respect to a specific violation of this part, no State attorney general may bring an action under this subsection against the person with respect to such violation during the pendency of that action.

(8) Application of CMP statute of limitation

A civil action may not be instituted with respect to a violation of this part unless an action to impose a civil money penalty may be instituted under subsection (a) with respect to such violation consistent with the second sentence of [section 1320a-7a\(c\)\(1\)](#) of this title.

(e) Allowing continued use of corrective action

Nothing in this section shall be construed as preventing the Office for Civil Rights of the Department of Health and Human Services from continuing, in its discretion, to use corrective action without a penalty in cases where the person did not know (and by exercising reasonable diligence would not have known) of the violation involved.

CREDIT(S)

(Aug. 14, 1935, c. 531, Title XI, § 1176, as added [Pub.L. 104-191, Title II, § 262\(a\)](#), Aug. 21, 1996, 110 Stat. 2028; amended [Pub.L. 111-5](#), Div. A, Title XIII, § 13410(a)(1), (d)(1) to (3), (e)(1), (2), (f), Feb. 17, 2009, 123 Stat. 271 to 276.)

[Notes of Decisions \(12\)](#)

Footnotes

- 1 So in original. Probably should be “(b)(2)(A)”.
- 2 So in original. Probably should be “are”.
- 3 So in original. Probably should be “(2)”.
- 4 So in original. The words “or damages” probably should appear after “penalty”.

42 U.S.C.A. § 1320d-5, 42 USCA § 1320d-5

Current through P.L. 118-158. Some statute sections may be more current, see credits for details.

End of Document

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United States Code Annotated

Title 42. The Public Health and Welfare

Chapter 7. Social Security (Refs & Annos)

Subchapter XI. General Provisions, Peer Review, and Administrative Simplification (Refs & Annos)

Part C. Administrative Simplification

42 U.S.C.A. § 1320d-6

§ 1320d-6. Wrongful disclosure of individually identifiable health information

Currentness

(a) Offense

A person who knowingly and in violation of this part--

- (1) uses or causes to be used a unique health identifier;
- (2) obtains individually identifiable health information relating to an individual; or
- (3) discloses individually identifiable health information to another person,

shall be punished as provided in subsection (b). For purposes of the previous sentence, a person (including an employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in [section 1320d-9\(b\)\(3\)](#) of this title) and the individual obtained or disclosed such information without authorization.

(b) Penalties

A person described in subsection (a) shall--

- (1) be fined not more than \$50,000, imprisoned not more than 1 year, or both;
- (2) if the offense is committed under false pretenses, be fined not more than \$100,000, imprisoned not more than 5 years, or both; and
- (3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than \$250,000, imprisoned not more than 10 years, or both.

CREDIT(S)

(Aug. 14, 1935, c. 531, Title XI, § 1177, as added [Pub.L. 104-191, Title II, § 262\(a\)](#), Aug. 21, 1996, 110 Stat. 2029; amended [Pub.L. 111-5](#), Div. A, Title XIII, § 13409, Feb. 17, 2009, 123 Stat. 271.)

[Notes of Decisions \(36\)](#)

42 U.S.C.A. § 1320d-6, 42 USCA § 1320d-6

Current through P.L. 118-158. Some statute sections may be more current, see credits for details.

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Opinion 1.1.1 Patient-Physician Relationships

The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. The relationship between a patient and a physician is based on trust, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest or obligations to others, to use sound medical judgment on patients' behalf, and to advocate for their patients' welfare.

A patient-physician relationship exists when a physician serves a patient's medical needs. Generally, the relationship is entered into by mutual consent between physician and patient (or surrogate).

However, in certain circumstances a limited patient-physician relationship may be created without the patient's (or surrogate's) explicit agreement. Such circumstances include:

- (a) When a physician provides emergency care or provides care at the request of the patient's treating physician. In these circumstances, the patient's (or surrogate's) agreement to the relationship is implicit.
- (b) When a physician provides medically appropriate care for a prisoner under court order, in keeping with ethics guidance on court-initiated treatment.
- (c) When a physician examines a patient in the context of an independent medical examination, in keeping with ethics guidance. In such situations, a limited patient-physician relationship exists.

AMA Principles of Medical Ethics: I,II,IV,VIII

Background report(s):

CEJA Report 3-A-16, Modernized *Code of Medical Ethics*

CEJA Report 1-A-01, The Patient-Physician Relationship

CEJA Report 3-A-16 Modernized Code of Medical Ethics

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- (b) When a physician provides medically appropriate care for a prisoner under court order, in keeping with ethics guidance on court-initiated treatment.
- (c) *When a physician examines a patient in the context of an independent medical examination, in keeping with ethics guidance. In such situations, a limited patient-physician relationship exists. [new guidance cross-references guidance in Opinion 1.2.6]*

AMA Principles of Medical Ethics: I,II,IV,VIII

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

CEJA Report 1-A-01

Subject: The Patient-Physician Relationship

Presented by: Herbert Rakatansky, MD, Chair

Presented to: Reference Committee on Amendments to Constitution and Bylaws
(William J. Mangold, Jr., MD, Chair)

Introduction

At the center of the history of the American Medical Association lies its *Code of Medical Ethics*. The original *Code* of 1847 promulgated an ethic that emphasized conduct rather than character. It was premised on the understanding that the very nature of the physician's responsibility consisted of caring for the sick and that this was a responsibility owed by all physicians to all patients.¹ Also, building upon the Hippocratic tradition, physicians were called upon to hold a sense of ethical obligation that rose above considerations of personal advancement.² According to one commentator, "the central moral commitment of the code was its dedication to something other than the physician's self-interest, that something being the primacy of the welfare of the patient."³

The current *Code*'s focus on the relationship between physician and patient is exemplified by the *Fundamental Elements of the Patient-Physician Relationship* issued in 1990.⁴ In particular, physicians are to foster this partnership by providing information and allowing for autonomous decision-making, acting respectfully and in a timely manner, preserving confidentiality, ensuring continuity of care, and facilitating access to care. Despite this list of features of the relationship patients can expect from physicians and which physicians must strive to fulfill, the very nature of the patient-physician relationship remains unexamined.

The patient-physician relationship, which is at the heart of the AMA's *Code of Medical Ethics*, is the focus of this report.

Conceptualizing the patient-physician relationship

According to one medical ethicist, there is no single characterization that can properly do justice to the patient-physician relationship "given the complexity of professional styles, patient expectations and values, and contexts in which the relationship is established."⁵ For example, patients treated for chronic diseases may have long-established relationships with their physicians, or may be interacting with a specialist for a single consult.

Irrespective of the circumstances of the encounter between patient and physician, medical ethicists have characterized it in terms of a moral activity. This has been found to arise from the condition that brings patients into contact with physicians, namely illness. "Healing is sought for concerns that go to the root of human existence: fears of death, deformity, and disability."⁶ Patients have been described in terms of their vulnerability, and consequently exploitable state,

Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

1 and their dependence on the medical expertise and the compassion of physicians. In order to
2 maintain good health or to secure the treatments that will alleviate their ills, patients, or surrogate
3 decision-makers on their behalf, agree to enter into relationships with physicians. At times, the
4 agreement to enter into a relationship is implied, such as when a patient is unconscious and in
5 need of emergency care, or when physicians provide a specific service at the request of the
6 treating physician (e.g. the services of a pathologist). Physicians also agree to enter the
7 relationship; either directly, as agents, or by previous contractual arrangements to treat a group of
8 patients. The relationship, therefore, is established by mutual agreement. In some rare instances,
9 such as legally mandated treatment as described in Opinion 2.065, “Court-Initiated Treatments in
10 Criminal Cases,”⁷ treatment may be provided by a physician even though a patient has not
11 consented to entering into a relationship. In such circumstances, physicians remain bound by the
12 same obligations.

13
14 Once the relationship has been established, patients should be confident that they are receiving
15 the best medical care their physicians can provide, uncompromised by external factors. However,
16 the medical profession currently finds itself amidst tensions between physicians’ altruistic
17 covenant to provide needed medical care to patients and the market ethos of profit-making.⁸

18 19 Ethical obligations of physicians

20
21 Trust is central to the patient-physician relationship. Physicians provide specialized knowledge
22 and expert skills that are relied upon by patients. Physicians also hold considerable control over
23 medical resources used for the benefit of patients.

24
25 Many ethicists have emphasized the obligation of fidelity that is owed whenever the physician
26 establishes a relationship with the patient.⁹ One important manifestation of this obligation of
27 fidelity is the ethical obligation not to abandon a patient, which would undermine physicians’
28 trustworthiness. CEJA Opinion 8.115, “Termination of the Physician-Patient Relationship”
29 embodies this obligation to ensure continuity of care. Viewed from a different perspective,
30 medicine is an act of “profession” whereby physicians promise to use their knowledge to help and
31 to heal.¹⁰

32
33 The patient-physician relationship is held to high standards of conduct, as embodied in the *Code*
34 *of Medical Ethics*. This characterization of the patient-physician relationship differs significantly
35 from the contractual view of the relationship in which patients seek care and physicians provide
36 it.¹¹ Ethically, it would be insufficient to view health care as an ordinary service and to allow
37 care that patients request from physicians to be governed by the maxim “let the buyer beware.”

38
39 However, much of the current health care delivery system operates according to the dynamics of
40 the market. According to many participants in this system, profit-making is a legitimate goal and
41 financial incentives are important tools in controlling health care resources. This reality confers
42 even greater importance onto the principal feature of the patient-physician relationship, which
43 require that patients’ interests be given priority. Therefore, external factors that may result in
44 compromising medical judgment deserve careful examination.

45 46 Conflicts of interest

47
48 Many ethicists have long argued that some effacement of self-interest is morally obligatory for
49 physicians.⁸ This notion is captured throughout the *Code of Medical Ethics*.

1 *Conflicts between physicians' and patients' interests*

2
3 Physicians' self-interest that may conflict with the interests of patients is addressed in
4 unambiguous terms in Opinion 8.03, "Conflicts of Interest: Guidelines," which states that "Under
5 no circumstances may physicians place their own financial interests above the welfare of their
6 patients (...) If a conflict develops between the physician's financial interest and the physician's
7 responsibilities to the patient, the conflict must be resolved to the patient's benefit."
8

9 More troubling in this era of managed care are some of the methods used to accomplish cost
10 containment. Specifically, various risk-bearing arrangements that affect physicians' incomes
11 according to their use of health care resources may lead to limitations that could be harmful to
12 patients. In Opinion 8.054, "Financial Incentives and the Practice of Medicine," physicians are
13 advised to evaluate financial incentives included in managed care contracts to ensure that quality
14 of patient care is not compromised by placing physicians' payments at excessive risk or by setting
15 unrealistic expectations for utilization. The Opinion also recommends that large financial
16 incentives should be limited in order to prevent physicians' personal financial concerns from
17 creating a conflict with their role as individual patient advocates.
18

19 *Conflicts between individual patients and patient populations*

20
21 Managed care's use of financial incentives to influence physicians' decision-making also has led
22 to a shift from patient-focused medicine to population-based medicine. In order to stay within
23 budgetary limits, physicians are urged, often through financial and other incentives, to consider
24 the impact of the decisions they make on an entire group of patients, rather than on a single
25 patient. Physicians who allow such incentives to color medical judgement become primarily
26 agents of the health plan rather than of individual patients.¹² It would seem more likely that
27 patients' trust in physicians will be best preserved if those who are ill can expect their physicians
28 to be advocates for optimal care and not just some minimal standard.¹² However, systemic
29 budgetary constraints may in fact prevent patients from obtaining access to the optimal level of
30 care necessary to treat a condition. Faced with such prospects, patients must find allies who will
31 assist them in gaining access to the resources needed to treat their condition. In an earlier
32 report,¹³ the Council clearly identified that physicians have a duty of patient advocacy that should
33 not be altered by the system of health care delivery, and that requires physicians to advocate for
34 any care they believe will materially benefit their patients.
35

36 Conclusion

37
38 The medical profession must strive to preserve the trust patients hold in their physicians. It
39 cannot abandon ethical standards to economic forces. As individual physicians advocate for the
40 care their individual patients require, so must the medical profession advocate for access to care
41 for all. Individual physicians must work to forge strong alliances with their own patients, and the
42 medical profession with the public, to preserve the integrity of the profession.
43

44 Recommendations

45
46 The Council recommends that the following be adopted and the remainder of the report be filed:
47

48 The practice of medicine, and its embodiment in the clinical encounter between a
49 patient and a physician, is fundamentally a moral activity that arises from the
50 imperative to care for patients and to alleviate suffering. The relationship
51 between patient and physician is based on trust and gives rise to physicians'

1 ethical obligations to place patients' welfare above their own self-interest and
2 above obligations to other groups, and to advocate for their patients' welfare.
3

4 A patient-physician relationship is generally created by mutual agreement
5 between physician and patient (or surrogate). In some instances the agreement is
6 implied, such as in emergency care or when physicians provide services at the
7 request of the treating physician. In rare instances, treatment without consent
8 may be provided under court order (see Opinion 2.065). Nevertheless, the
9 physician's obligations to the patient remain intact.
10

11 Within the patient-physician relationship, a physician is ethically required to use
12 sound medical judgment, holding the best interests of the patient as paramount.

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Trump's HHS nominee Robert F. Kennedy Jr. reassures pro-life senators with policy plans



Robert F. Kennedy Jr., President-elect Donald Trump's nominee to be secretary of Health and Human Services, arrives for meetings at the Hart Senate Office Building on Capitol Hill on Dec. 16, 2024, in Washington, D.C. | Credit: Chip Somodevilla/Getty Images



By **Tyler Arnold**

Washington, D.C. Newsroom, Dec 18, 2024 / 17:50 pm

Robert F. Kennedy Jr. is reassuring Republican senators that he will back certain pro-life policies if the Senate confirms him to lead the U.S. Department of Health and Human Services (HHS).

In November, U.S. President-elect Donald Trump **nominated Kennedy** to serve as the United States secretary of the HHS, a position that requires Senate confirmation. HHS oversees 10 agencies, including the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC).



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Although Kennedy has supported legal abortion for his entire public career, he told pro-life senators in closed-door meetings that he would oppose taxpayer funds for abortion domestically and abroad and restore conscience protections.

"Today I got to sit down with [Kennedy] — we had a substantive discussion about American health care ... [and] a good discussion, at length, about pro-life policies at HHS," Sen. Josh Hawley, R-Missouri, said in [a series of posts on X](#).

According to Hawley, Kennedy told him that, if confirmed, he would reinstate [the Mexico City Policy](#), which ends federal funding for overseas organizations that promote abortion. Trump reinstated the Mexico City Policy during his first term and said in [an October interview with EWTN News](#) that he would consider doing so again in a second term.

Hawley said Kennedy's plans include "ending taxpayer funding for abortions domestically" and "reinstating the bar on Title X funds going to organizations that promote abortion." He said that Kennedy also "pledged to reinstate conscience protections for health care providers."

Sen. Tommy Tuberville, R-Alabama, told reporters that he and Kennedy also talked about abortion, saying: "The big thing about abortion is that he's telling everybody ... whatever President Trump [supports], I'm going to back him 100%."

"Basically, [Kennedy] and President Trump have sat down and talked about it and both of them came to an agreement," Tuberville said. "Roe v. Wade is gone, [abortion has] gone back to the states. Let the people vote on it."



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[Kennedy's] first thing is [that] we have too many abortions," Trump said. ... His follow-up to that is [that he is] serving at the will of the president of the United States. ... I think that should clear up that question for anyone."

Sen. Tim Scott, R-South Carolina, said **in a post on X** that he also spoke with Kennedy about abortion.

"I had a productive discussion with Robert F. Kennedy Jr. this evening about the future of our nation's health care system, preventing taxpayer-funded abortion, and Americans' long-term well-being," Scott said.

During his independent presidential campaign, Kennedy **first endorsed** abortion in all stages of pregnancy, including late-term abortion. He later **retracted that position** and said he would back restrictions at the point of fetal viability.

Kennedy also said during his campaign that **he would support** a "massive subsidized day care initiative" to reduce abortion without limiting legal access.

No word on chemical abortions

(Story continues below)

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Tuberville, however, said that he did not speak with Kennedy about chemical abortions, which are regulated by the FDA. Trump himself **has said he will not** restrict access to **the abortion pill mifepristone**. Chemical abortions account for about half of all abortions in the country.



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Mifepristone kills the child by blocking the hormone progesterone, which cuts off the supply of oxygen and nutrients. A second pill, misoprostol, is taken between 24 to 48 hours after mifepristone to induce contractions meant to expel the child's body from the mother, essentially inducing labor.

Pro-life advocates **have been urging** the incoming administration to restrict abortion drugs. Many activists have argued that the executive branch could prohibit the delivery of abortion drugs in the mail by **enforcing the Comstock Act** — a plan that has not been embraced by Trump.

Tags: Catholic News, President Donald Trump, HHS - Department for Health and Human Services, Abortion in the United States, Robert F. Kennedy Jr., Pro-Life News



Tyler Arnold is a staff reporter for Catholic News Agency, based in EWTN News' Washington Bureau. He previously worked at The Center Square and has been published in a variety of outlets, including The Associated Press, National Review, The American Conservative, and The Federalist.

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- 1 Trump at National Prayer Breakfast announces task force to end anti-Christian bias
- 2 Pope Francis reiterates desire for 'full unity' among Christians
- 3 Pope Francis urges all Catholics to be 'missionaries of hope' through prayer and action
- 4 Rubio says State Department will exempt select USAID programs from freeze
- 5 Missouri diocese opens sacred music consultation process after hymn 'bans' rescinded



UPDATE: Trump picks several Catholics for Cabinet: Kennedy, Rubio, Stefanik, Ratcliffe, Duffy

Nov 18, 2024

The 45th and soon-to-be 47th president made more than a dozen announcements within 10 days of his electoral victory over Vice President Kamala Harris.



Trump could restrict transgender surgeries for kids in second term, policy analysts say

Nov 11, 2024

"The left-wing gender insanity being pushed in our children is an act of child abuse," Trump said earlier this year in a campaign video.



More than 100 members of Congress urge investigation into abortion funding

Nov 27, 2024

One hundred and twelve members of Congress signed the Nov. 22 letter spearheaded by House Pro-Life Caucus Co-Chair Rep. Chris Smith, R-New Jersey.



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Photograph by Philip Montgomery for TIME

POLITICS DONALD TRUMP

How Far Trump Would Go

ERIC CORTELLESSA / PALM BEACH, FLA. @EricCortellessa | April 30, 2024

In exclusive interviews, the former President lays out a second-term agenda that would reshape America and its role in the world.

This feature was published in April 2024.

Donald Trump thinks he's identified a crucial mistake of his first term: He was too nice.

We've been [talking for more than an hour](#) on April 12 at his fever-dream palace in Palm Beach. Aides lurk around the perimeter of a gilded dining room overlooking the manicured lawn. When one nudges me to wrap up the interview, I bring up the many former Cabinet officials who refuse to endorse Trump this time. Some have publicly warned that he poses a danger to the Republic. Why should voters trust you, I ask, when some of the people who observed you most closely do not?

As always, Trump punches back, denigrating his former top advisers. But beneath the typical torrent of invective, there is a larger lesson he has taken away. "I let them quit

because I have a heart. I don't want to embarrass anybody," Trump says. "I don't think I'll do that again. From now on, I'll fire."

Six months from the 2024 presidential election, Trump is better positioned to win the White House than at any point in either of his previous campaigns. He leads Joe Biden by slim margins in most polls, including in several of the seven swing states likely to determine the outcome. But I had not come to ask about the election, the disgrace that followed the last one, or how he has become the first former—and perhaps future—American President to [face a criminal trial](#). I wanted to know what Trump would do if he wins a second term, to hear his vision for the nation, in his own words.



Photograph by Philip Montgomery for TIME
The former President, at Mar-a-Lago on April 12, is rallying the right at home and seeking common cause with autocratic leaders abroad.



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What emerged in two interviews with Trump, and conversations with more than a dozen of his closest advisers and confidants, were the outlines of an imperial presidency that would reshape America and its role in the world. To carry out a deportation operation designed to remove more than 11 million people from the country, Trump told me, he would be willing to build migrant detention camps and deploy the U.S. military, both at the border and inland. He would let red states monitor women's pregnancies and prosecute those who violate abortion bans. He would, at his personal discretion, withhold funds appropriated by Congress, according to top advisers. He would be willing to fire a U.S. Attorney who doesn't carry out his order to prosecute someone, breaking with a tradition of independent law enforcement that dates from America's founding. He is weighing pardons for every one of his supporters accused of attacking the U.S. Capitol on Jan. 6, 2021, more than 800 of whom have pleaded guilty or been convicted by a jury. He might not come to the aid of an attacked ally in Europe or Asia if he felt that country wasn't paying enough for its own defense. He would gut the U.S. civil service, deploy the National Guard to American cities as he sees fit, close the White House pandemic-preparedness office, and staff his Administration with acolytes who back his false assertion that the 2020 election was stolen.

Trump remains the same guy, with the same goals and grievances. But in person, if anything, he appears more assertive and confident. "When I first got to Washington, I knew very few people," he says. "I had to rely on people." Now he is in charge. The arranged marriage with the timorous Republican Party stalwarts is over; the old guard is vanquished, and the people who remain are his people. Trump would enter a second term backed by a slew of policy shops staffed by loyalists who have drawn up detailed plans in service of his agenda, which would concentrate the powers of the state in the hands of a man whose appetite for power appears all but insatiable. "I don't think it's a big mystery what his agenda would be," says his close adviser Kellyanne Conway. "But I think people will be surprised at the alacrity with which he will take action."



- [The 7 States That Will Decide the Election](#)
- [A Guide to Kamala Harris' Views on Abortion, the Economy, and More](#)
- [See the Most Memorable Looks From the Republican National Convention](#)
- [How Far Trump Would Go](#)
- [Read the Full Transcripts of Donald Trump's Interviews With TIME](#)

The courts, the Constitution, and a Congress of unknown composition would all have a say in whether Trump's objectives come to pass. The machinery of Washington has a range of defenses: leaks to a free press, whistle-blower protections, the oversight of inspectors general. The same deficiencies of temperament and judgment that hindered him in the past remain present. If he wins, Trump would be a lame duck—contrary to the suggestions of some supporters, he tells TIME he would not seek to overturn or ignore the Constitution's prohibition on a third term. Public opinion would also be a powerful check. Amid a popular outcry, Trump was forced to scale back some of his most draconian first-term initiatives, including the policy of separating migrant families. As George Orwell wrote in 1945, the ability of governments to carry out their designs "depends on the general temper in the country."

Every election is billed as a national turning point. This time that rings true. To supporters, the prospect of Trump 2.0, unconstrained and backed by a disciplined movement of true believers, offers revolutionary promise. To much of the rest of the nation and the world, it represents an alarming risk. A second Trump term could bring “the end of our democracy,” says presidential historian Douglas Brinkley, “and the birth of a new kind of authoritarian presidential order.”

Trump steps onto the patio at Mar-a-Lago near dusk. The well-heeled crowd eating Wagyu steaks and grilled branzino pauses to applaud as he takes his seat. On this gorgeous evening, the club is a MAGA mecca. Billionaire donor Steve Wynn is here. So is [Speaker of the House Mike Johnson](#), who is dining with the former President after a joint press conference proposing legislation to prevent noncitizens from voting. Their voting in federal elections is already illegal, and extremely rare, but remains a Trumpian fixation that the embattled Speaker appeared happy to co-sign in exchange for the political cover that standing with Trump provides.

At the moment, though, Trump’s attention is elsewhere. With an index finger, he swipes through an iPad on the table to curate the restaurant’s soundtrack. The playlist veers from Sinead O’Connor to James Brown to *The Phantom of the Opera*. And there’s a uniquely Trump choice: a rendition of “The Star-Spangled Banner” sung by a choir of defendants imprisoned for attacking the U.S. Capitol on Jan. 6, interspersed with a recording of Trump reciting the Pledge of Allegiance. This has become a staple of his rallies, converting the ultimate symbol of national unity into a weapon of factional devotion.

The spectacle picks up where his first term left off. The [events of Jan. 6](#), during which a pro-Trump mob attacked the center of American democracy in an effort to subvert the peaceful transfer of power, was a profound stain on his legacy. Trump has sought to recast an insurrectionist riot as an act of patriotism. “I call them the J-6 patriots,” he says. When I ask whether he would consider pardoning every one of them, he says, “Yes, absolutely.” As Trump faces dozens of felony charges, including for election interference, conspiracy to defraud the United States, willful retention of national-security secrets, and falsifying business records to conceal hush-money payments, he has tried to turn legal peril into a badge of honor.



In a second term, Trump’s influence on American democracy would extend far beyond pardoning powers. Allies are laying the groundwork to restructure the presidency in line with a doctrine called the unitary executive theory, which holds that many of the constraints imposed on the White House by legislators and the courts should be swept away in favor of a more powerful Commander in Chief.

Read More: [Fact-Checking What Donald Trump Said In His Interviews With TIME](#)

Nowhere would that power be more momentous than at the Department of Justice. Since the nation’s earliest days, Presidents have generally kept a respectful distance from

Senate-confirmed law-enforcement officials to avoid exploiting for personal ends their enormous ability to curtail Americans' freedoms. But Trump, burned in his first term by multiple investigations directed by his own appointees, is ever more vocal about imposing his will directly on the department and its far-flung investigators and prosecutors.

[video id=FlgFvoZe autostart="viewable"]

In our Mar-a-Lago interview, Trump says he might fire U.S. Attorneys who refuse his orders to prosecute someone: "It would depend on the situation." He's told supporters he would seek retribution against his enemies in a second term. Would that include [Fani Willis](#), the Atlanta-area district attorney who charged him with election interference, or Alvin Bragg, the Manhattan DA in the Stormy Daniels case, who Trump has previously said should be prosecuted? Trump demurs but offers no promises. "No, I don't want to do that," he says, before adding, "We're gonna look at a lot of things. What they've done is a terrible thing."

Trump has also vowed to appoint a "real special prosecutor" to go after Biden. "I wouldn't want to hurt Biden," he tells me. "I have too much respect for the office." Seconds later, though, he suggests Biden's fate may be tied to an upcoming Supreme Court ruling on whether Presidents can face criminal prosecution for acts committed in office. "If they said that a President doesn't get immunity," says Trump, "then Biden, I am sure, will be prosecuted for all of his crimes." (Biden has not been charged with any, and a House Republican effort to impeach him has failed to unearth evidence of any crimes or misdemeanors, high or low.)

Read More: [Trump Says 'Anti-White Feeling' Is a Problem in the U.S.](#)

Such moves would be potentially catastrophic for the credibility of American law enforcement, scholars and former Justice Department leaders from both parties say. "If he ordered an improper prosecution, I would expect any respectable U.S. Attorney to say no," says Michael McConnell, a former U.S. appellate judge appointed by President George W. Bush. "If the President fired the U.S. Attorney, it would be an enormous firestorm." McConnell, now a Stanford law professor, says the dismissal could have a cascading effect similar to the [Saturday Night Massacre](#), when President Richard Nixon ordered top DOJ officials to remove the special counsel investigating Watergate. Presidents have the constitutional right to fire U.S. Attorneys, and typically replace their predecessors' appointees upon taking office. But discharging one specifically for refusing a President's order would be all but unprecedented.



Trump's radical designs for presidential power would be felt throughout the country. A main focus is the southern border. Trump says he plans to sign orders to reinstall many of the same policies from his first term, such as the Remain in Mexico program, which requires that non-Mexican asylum seekers be sent south of the border until their court dates, and [Title 42](#), which allows border officials to expel migrants without letting them apply for asylum. Advisers say he plans to cite record border crossings and fentanyl- and child-trafficking as justification for reimposing the emergency measures. He would direct federal funding to resume construction of the border wall, likely by allocating

money from the military budget without congressional approval. The capstone of this program, advisers say, would be a massive deportation operation that would target millions of people. Trump made similar pledges in his first term, but says he plans to be more aggressive in a second. "People need to be deported," says Tom Homan, a top Trump adviser and former acting head of Immigration and Customs Enforcement. "No one should be off the table."

Read More: [The Story Behind TIME's 'If He Wins' Trump Cover](#)

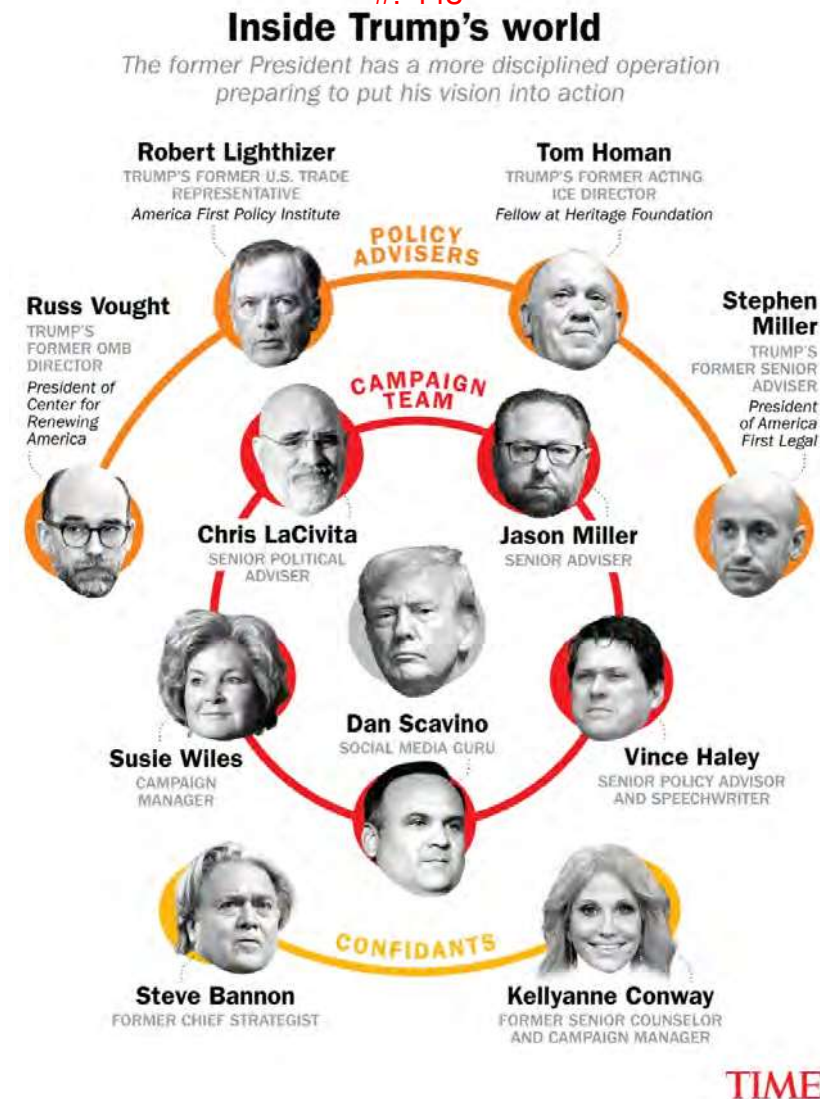
For an operation of that scale, Trump says he would rely mostly on the National Guard to round up and remove undocumented migrants throughout the country. "If they weren't able to, then I'd use [other parts of] the military," he says. When I ask if that means he would override the [Posse Comitatus](#) Act—an 1878 law that prohibits the use of military force on civilians—Trump seems unmoved by the weight of the statute. "Well, these aren't civilians," he says. "These are people that aren't legally in our country." He would also seek help from local police and says he would deny funding for jurisdictions that decline to adopt his policies. "There's a possibility that some won't want to participate," Trump says, "and they won't partake in the riches."

As President, Trump nominated three Supreme Court Justices who voted to overturn *Roe v. Wade*, and he claims credit for his role in ending a constitutional right to an abortion. At the same time, he has sought to defuse a potent campaign issue for the Democrats by saying he wouldn't sign a federal ban. In our interview at Mar-a-Lago, he declines to commit to vetoing any additional federal restrictions if they came to his desk. More than 20 states now have full or partial abortion bans, and Trump says those policies should be left to the states to do what they want, including monitoring women's pregnancies. "I think they might do that," he says. When I ask whether he would be comfortable with states prosecuting women for having abortions beyond the point the laws permit, he says, "It's irrelevant whether I'm comfortable or not. It's totally irrelevant, because the states are going to make those decisions." President Biden has said he would fight state anti-abortion measures in court and with regulation.

Trump's allies don't plan to be passive on abortion if he returns to power. The Heritage Foundation has called for enforcement of a 19th century statute that would outlaw the mailing of abortion pills. The Republican Study Committee (RSC), which includes more than 80% of the House GOP conference, included in its 2025 budget proposal the Life at Conception Act, which says the right to life extends to "the moment of fertilization." I ask Trump if he would veto that bill if it came to his desk. "I don't have to do anything about vetoes," Trump says, "because we now have it back in the states."

Presidents typically have a narrow window to pass major legislation. Trump's team is eyeing two bills to kick off a second term: a border-security and immigration package, and an extension of his 2017 tax cuts. Many of the latter's provisions expire early in 2025: the tax cuts on individual income brackets, 100% business expensing, the doubling of the estate-tax deduction. Trump is planning to intensify his protectionist agenda, telling me he's considering a tariff of more than 10% on all imports, and perhaps even a 100% tariff on some Chinese goods. Trump says the tariffs will liberate the U.S. economy from being at the mercy of foreign manufacturing and spur an industrial renaissance in the U.S. When I point out that independent analysts estimate Trump's first term tariffs on thousands of products, including steel and aluminum, solar panels, and washing machines, may have cost the U.S. \$316 billion and more than 300,000 jobs, by one account, he dismisses these experts out of hand. His advisers argue that the average yearly inflation rate in his first term—under 2%—is evidence that his tariffs won't raise prices.

Since leaving office, Trump has tried to engineer a caucus of the compliant, clearing primary fields in Senate and House races. His hope is that GOP majorities replete with MAGA diehards could rubber-stamp his legislative agenda and nominees. Representative Jim Banks of Indiana, a former RSC chairman and the GOP nominee for the state's open Senate seat, recalls an August 2022 RSC planning meeting with Trump at his residence in Bedminster, N.J. As the group arrived, Banks recalls, news broke that Mar-a-Lago had been raided by the FBI. Banks was sure the meeting would be canceled. Moments later, Trump walked through the doors, defiant and pledging to run again. "I need allies there when I'm elected," Banks recalls Trump saying. The difference in a second Trump term, Banks says now, "is he's going to have the backup in Congress that he didn't have before."



Trump's intention to remake America's relations abroad may be just as consequential. Since its founding, the U.S. has sought to build and sustain alliances based on the shared values of political and economic freedom. Trump takes a much more transactional approach to international relations than his predecessors, expressing disdain for what he views as free-riding friends and appreciation for authoritarian leaders like President Xi Jinping of China, Prime Minister Viktor Orban of Hungary, or former President Jair Bolsonaro of Brazil.

That's one reason America's traditional allies were horrified when Trump recently said at a campaign rally that Russia could "do whatever the hell they want" to a NATO country he believes doesn't spend enough on collective defense. That wasn't idle bluster, Trump tells me. "If you're not going to pay, then you're on your own," he says. Trump has long said the alliance is ripping the U.S. off. Former NATO Secretary-General Jens Stoltenberg credited Trump's first-term threat to pull out of the alliance with spurring other members to add more than \$100 billion to their defense budgets.

But an insecure NATO is as likely to accrue to Russia's benefit as it is to America's. President Vladimir Putin's 2022 invasion of Ukraine looks to many in Europe and the U.S. like a test of his broader vision to reconstruct the Soviet empire. Under Biden and a bipartisan Congress, the U.S. has sent more than \$100 billion to Ukraine [to defend itself](#). It's unlikely Trump would extend the same support to Kyiv. After Orban visited Mar-a-Lago in March, he said Trump "wouldn't give a penny" to Ukraine. "I wouldn't give unless Europe starts equalizing," Trump hedges in our interview. "If Europe is not going to pay, why should we pay? They're much more greatly affected. We have an ocean in

between us. They don't." (E.U. nations have given more than \$100 billion in aid to Ukraine as well.)

Read More: [Read the Full Transcripts of Donald Trump's Interviews With TIME](#)

Trump has historically been reluctant to criticize or confront Putin. He sided with the Russian autocrat over his own intelligence community when it asserted that Russia interfered in the 2016 election. Even now, Trump uses Putin as a foil for his own political purposes. When I asked Trump why he has not called for the release of [Wall Street Journal](#) reporter Evan Gershkovich, who has been unjustly held on spurious charges in a Moscow prison for a year, Trump says, "I guess because I have so many other things I'm working on." Gershkovich should be freed, he adds, but he doubts it will happen before the election. "The reporter should be released and he will be released," Trump tells me. "I don't know if he's going to be released under Biden. I would get him released."

America's Asian allies, like its European ones, may be on their own under Trump. Taiwan's Foreign Minister recently said aid to Ukraine was critical in deterring Xi from invading the island. Communist China's leaders "have to understand that things like that can't come easy," Trump says, but he declines to say whether he would come to Taiwan's defense.

Trump is less cryptic on current U.S. troop deployments in Asia. If South Korea doesn't pay more to support U.S. troops there to deter Kim Jong Un's increasingly belligerent regime to the north, Trump suggests the U.S. could withdraw its forces. "We have 40,000 troops that are in a precarious position," he tells TIME. (The number is actually 28,500.) "Which doesn't make any sense. Why would we defend somebody? And we're talking about a very wealthy country."

Transactional isolationism may be the main strain of Trump's foreign policy, but there are limits. Trump says he would join Israel's side in a confrontation with Iran. "If they attack Israel, yes, we would be there," he tells me. He says he has come around to the now widespread belief in Israel that a Palestinian state existing side by side in peace is increasingly unlikely. "There was a time when I thought two-state could work," he says. "Now I think two-state is going to be very, very tough."

Yet even his support for Israel is not absolute. He's criticized Israel's handling of its war against Hamas, which has killed more than 30,000 Palestinians in Gaza, and has called for the nation to "get it over with." When I ask whether he would consider withholding U.S. military aid to Israel to push it toward winding down the war, he doesn't say yes, but he doesn't rule it out, either. He is [sharply critical](#) of Israeli Prime Minister Benjamin Netanyahu, once a close ally. "I had a bad experience with Bibi," Trump says. In his telling, a January 2020 U.S. operation to assassinate a top Iranian general was supposed to be a joint attack until Netanyahu backed out at the last moment. "That was something I never forgot," he says. He blames Netanyahu for failing to prevent the Oct. 7 attack, when Hamas militants infiltrated southern Israel and killed nearly 1,200 people amid acts of brutality including burning entire families alive and raping women and girls. "It happened on his watch," Trump says.

On the second day of Trump's New York trial on April 17, I stand behind the packed counter of the Sanaa Convenience Store on 139th Street and Broadway, waiting for Trump to drop in for a postcourt campaign stop. He [chose the bodega](#) for its history. In 2022, one of the store's clerks fatally stabbed a customer who attacked him. Bragg, the Manhattan DA, charged the clerk with second-degree murder. (The charges were later dropped amid public outrage over video footage that appeared to show the clerk acting in self-defense.) A baseball bat behind the counter alludes to lingering security concerns. When Trump arrives, he asks the store's co-owner, Maad Ahmed, a Yemeni immigrant, about safety. "You should be allowed to have a gun," Trump tells Ahmed. "If you had a gun, you'd never get robbed."

On the campaign trail, Trump uses crime as a cudgel, painting urban America as a savage hell-scape even though violent crime has declined in recent years, with homicides sinking 6% in 2022 and 13% in 2023, according to the FBI. When I point this out, Trump tells me he thinks the data, which is collected by state and local police departments, is rigged. "It's a lie," he says. He has pledged to send the National Guard into cities

struggling with crime in a second term—possibly without the request of governors—and plans to approve Justice Department grants only to cities that adopt his preferred policing methods like stop-and-frisk.

To critics, Trump's preoccupation with crime is a racial dog whistle. In polls, large numbers of his supporters have expressed the view that antiwhite racism now represents a greater problem in the U.S. than the systemic racism that has long afflicted Black Americans. When I ask if he agrees, Trump does not dispute this position. "There is a definite antiwhite feeling in the country," he tells TIME, "and that can't be allowed either." In a second term, advisers say, a Trump Administration would rescind Biden's Executive Orders designed to boost diversity and racial equity.



Trump's ability to campaign for the White House in the midst of an unprecedented criminal trial is the product of a more professional campaign operation that has avoided the infighting that plagued past versions. "He has a very disciplined team around him," says Representative Elise Stefanik of New York. "That is an indicator of how disciplined and focused a second term will be." That control now extends to the party writ large. In 2016, the GOP establishment, having failed to derail Trump's campaign, surrounded him with staff who sought to temper him. Today the party's permanent class have either devoted themselves to the gospel of MAGA or given up. Trump has cleaned house at the Republican National Committee, installing handpicked leaders—including his daughter-in-law—who have reportedly imposed loyalty tests on prospective job applicants, asking whether they believe the false assertion that the 2020 election was stolen. (The RNC has denied there is a litmus test.) Trump tells me he would have trouble hiring anyone who admits Biden won: "I wouldn't feel good about it."

Policy groups are creating a government-in-waiting full of true believers. The Heritage Foundation's Project 2025 has drawn up plans for legislation and Executive Orders as it trains prospective personnel for a second Trump term. The Center for Renewing America, led by Russell Vought, Trump's former director of the Office of Management and Budget, is dedicated to disempowering the so-called administrative state, the collection of bureaucrats with the power to control everything from drug-safety determinations to the contents of school lunches. The America First Policy Institute is a research haven of pro-Trump right-wing populists. America First Legal, led by Trump's immigration adviser Stephen Miller, is mounting court battles against the Biden Administration.

The goal of these groups is to put Trump's vision into action on day one. "The President never had a policy process that was designed to give him what he actually wanted and campaigned on," says Vought. "[We are] sorting through the legal authorities, the mechanics, and providing the momentum for a future Administration." That includes a litany of boundary-pushing right-wing policies, including slashing Department of Justice funding and cutting climate and environmental regulations.

Read More: [Fact-Checking What Donald Trump Said in His 2024 Interviews With TIME](#)

446

Trump's campaign says he would be the final decision-maker on which policies suggested by these organizations would get implemented. But at the least, these advisers could form the front lines of a planned march against what Trump dubs the Deep State, marrying bureaucratic savvy to their leader's anti-bureaucratic zeal. One weapon in Trump's second-term "War on Washington" is a wonky one: restoring the power of impoundment, which allowed Presidents to withhold congressionally appropriated funds. Impoundment was a favorite maneuver of Nixon, who used his authority to freeze funding for subsidized housing and the Environmental Protection Agency. Trump and his allies plan to challenge a 1974 law that prohibits use of the measure, according to campaign policy advisers.

Another inside move is the enforcement of Schedule F, which allows the President to fire nonpolitical government officials and which Trump says he would embrace. "You have some people that are protected that shouldn't be protected," he says. A senior U.S. judge offers an example of how consequential such a move could be. Suppose there's another pandemic, and President Trump wants to push the use of an untested drug, much as he did with hydroxychloroquine during COVID-19. Under Schedule F, if the drug's medical reviewer at the Food and Drug Administration refuses to sign off on its use, Trump could fire them, and anyone else who doesn't approve it. The Trump team says the President needs the power to hold bureaucrats accountable to voters. "The mere mention of Schedule F," says Vought, "ensures that the bureaucracy moves in your direction."

It can be hard at times to discern Trump's true intentions. In his interviews with TIME, he often sidestepped questions or answered them in contradictory ways. There's no telling how his ego and self-destructive behavior might hinder his objectives. And for all his norm-breaking, there are lines he says he won't cross. When asked if he would comply with all orders upheld by the Supreme Court, Trump says he would.

But his policy preoccupations are clear and consistent. If Trump is able to carry out a fraction of his goals, the impact could prove as transformative as any presidency in more than a century. "He's in full war mode," says his former adviser and occasional confidant Stephen Bannon. Trump's sense of the state of the country is "quite apocalyptic," Bannon says. "That's where Trump's heart is. That's where his obsession is."



These obsessions could once again push the nation to the brink of crisis. Trump does not dismiss the possibility of political violence around the election. "If we don't win, you know, it depends," he tells TIME. "It always depends on the fairness of the election." When I ask what he meant when he baselessly claimed on Truth Social that a stolen election "allows for the termination of all rules, regulations and articles, even those found in the Constitution," Trump responded by denying he had said it. He then complained about the "Biden-inspired" court case he faces in New York and suggested that the "fascists" in America's government were its greatest threat. "I think the enemy from within, in many cases, is much more dangerous for our country than the outside enemies of China, Russia, and various others," he tells me.

Toward the end of our conversation at Mar-a-Lago, I ask Trump to explain another troubling comment he made: that he wants to be dictator for a day. It came during a Fox

News town hall with Sean Hannity, who gave Trump an opportunity to allay concerns that he would abuse power in office or seek retribution against political opponents. Trump said he would not be a dictator—"except for day one," he added. "I want to close the border, and I want to drill, drill, drill."

Trump says that the remark "was said in fun, in jest, sarcastically." He compares it to an infamous moment from the 2016 campaign, when he encouraged the Russians to hack and leak Hillary Clinton's emails. In Trump's mind, the media sensationalized those remarks too. But the Russians weren't joking: among many other efforts to influence the core exercise of American democracy that year, they hacked the Democratic National Committee's servers and disseminated its emails through WikiLeaks.

Whether or not he was kidding about bringing a tyrannical end to our 248-year experiment in democracy, I ask him, Don't you see why many Americans see such talk of dictatorship as contrary to our most cherished principles? Trump says no. Quite the opposite, he insists. "I think a lot of people like it." —*With reporting by Leslie Dickstein, Simmone Shah, and Julia Zorthian*

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Mandate *for* Leadership

The Conservative Promise

Project 2025

PRESIDENTIAL TRANSITION PROJECT

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Department of Health and Human Services

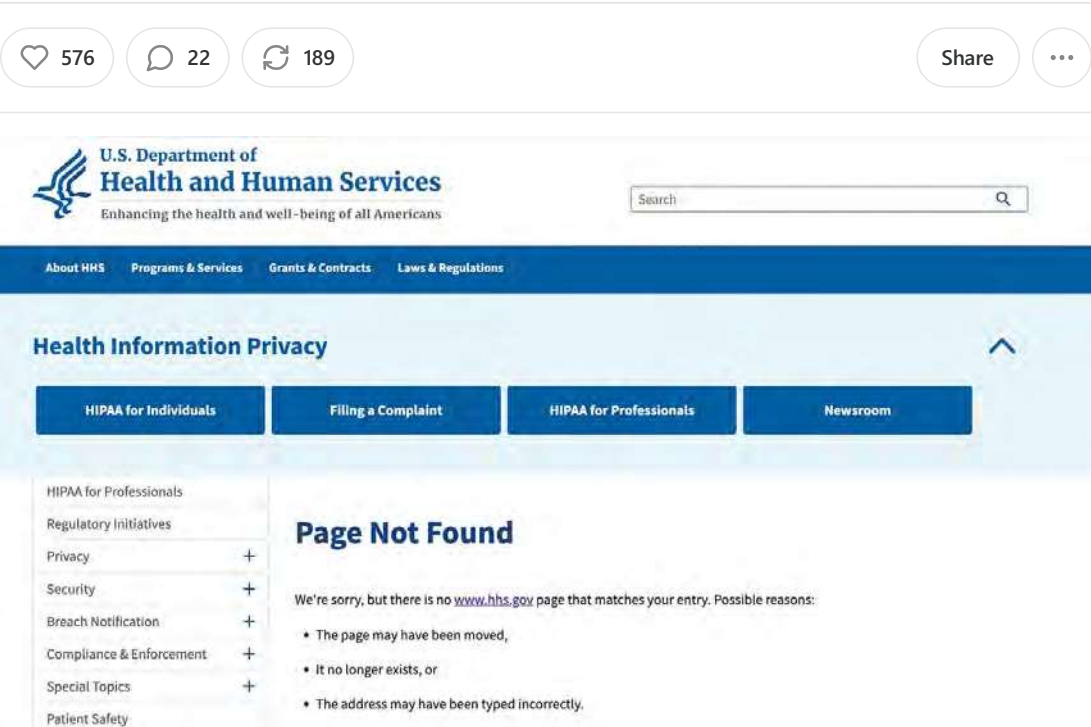
- **OCR should withdraw its Health Insurance Portability and Accountability Act (HIPAA)⁸⁶ guidance on abortion.** OCR should withdraw its June 2022 guidance⁸⁷ that purports to address patient privacy concerns following the *Dobbs* decision but is actually a politicized statement in favor of abortion and against *Dobbs*. HIPAA covers patients in the womb, but this guidance treats them as nonpersons contrary to law. The guidance is unnecessary and contributes to ideologically motivated fearmongering about abortion after *Dobbs*.

AUTHOR'S NOTE: The preparation of this chapter was a collective enterprise of selfless individuals involved in the 2025 Presidential Transition Project. All contributors to this chapter are listed at the front of this volume and include former officials in the U.S. Department of Health and Human Services and other agencies, as well as academics, attorneys, and experts in the health care and insurance fields.

Breaking: Trump is Scrubbing HIPAA Info off HHS Website

The White House is deleting information on reproductive health privacy and discrimination at pharmacies

JESSICA VALENTI
FEB 03, 2025



In yet another purge of vital health data, the Trump administration has scrubbed information about HIPAA protections for reproductive rights from the Department of Health and Human Services (HHS) website. They've also erased guidance on pharmacies' obligation not to discriminate against patients seeking reproductive health care.¹

This comes as the White House continues its [deletions](#) and ["modifications"](#) of CDC documents related to sexual and reproductive health, intimate partner violence, LGBTQ issues, and more.

And while [we knew](#) that HHS was deleting pages containing the word 'abortion,' this latest scrub is something more—a worrying road map of policies to come.

The deletions discovered by *Abortion, Every Day* indicate that it's likely **the White House will roll back privacy protections for reproductive health data**, making it easier for law enforcement, prosecutors, and attorneys general to access women's abortion records. And the removal of guidance on discrimination at pharmacies is a

sign that **the Trump administration will allow extremist pharmacists to deny women prescriptions to birth control**—or anything else they oppose.

Let's get into the details:

[HIPAA, the Health Insurance Portability and Accountability Act](#), is a federal law protecting private health information. Under Biden, [HHS expanded HIPAA protections](#) to bar health care and insurance providers from sharing reproductive health data that could be used in criminal or civil cases against abortion patients or providers.

For example, if a Texas woman traveled to New Mexico for an abortion, the rule prevented her doctors from sharing her identity or health records with law enforcement or bounty-hunting anti-abortion activists.

The Biden rule infuriated Republicans, who were desperate to access women's private medical records—despite their repeated (and unconvincing) insistence that they *don't* want to punish abortion patients.

In 2023, for example, [Abortion, Every Day reported](#) that 19 Republican attorneys general were pressuring HHS to allow them access to the records of out-of-state abortion patients. And in September 2024, Texas Attorney General Ken Paxton [sued the Biden administration](#) over the new HIPAA rule, arguing that it “would unlawfully restrict state law enforcement investigations.”

That's why these protections matter: They safeguard providers and patients from zealous prosecutions and ensure women seeking abortions don't have to worry about their private medical records falling into the wrong hands.

REPUBLICANS KNOW THAT HEADLINES ABOUT GIVING PROSECUTORS ACCESS TO WOMEN'S OUT-OF-STATE ABORTION RECORDS WOULD BE A DISASTER

Of course, we always expected the Trump administration to revoke these protections—after all, they're undoing everything Biden put in place on abortion. But they haven't pulled the trigger yet. And I'd bet Republicans know that headlines about giving prosecutors access to women's out-of-state abortion records would be a disaster for them. Especially now, when abortion rights are more popular than ever.

It makes me wonder if the deletions are part of a slow rollout of that eventual repeal.

While the rule still stands, the White House is making it as hard as possible for Americans to find out about their repro-related privacy rights. [One of the scrubbed pages](#), for example, laid out how patients and providers can navigate the expanded HIPAA protections. The HHS also deleted information on how patients can protect their reproductive health data while using cell phones and tablets.

Certain pages on reproductive rights privacy remain up at HHS—like the text of the rule itself—but without those purged pages, the information is buried. (Which, I’m sure, is the point.)

Again: This isn’t just a broad erasure of anything related to reproductive rights, but a targeted excising.

Under Biden, for example, the HHS issued guidance banning pharmacists from refusing medication to women based on “pregnancy or related conditions”—something the agency explicitly defined as sex discrimination. But Trump’s HHS wants to let extremist pharmacists refuse women medication for any reason they declare against their ‘conscience.’ In fact, as that guidance was deleted from the HHS site, the agency [announced](#) that they’ll “strengthen enforcement” of “conscience” rules.

If a pharmacist believes unmarried women shouldn’t have premarital sex, for example, the White House wants to him to be able to deny that patient birth control. Never mind if the woman lives in a rural area and there’s only one pharmacist in her county. Remember: This was one of the policy directives outlined in [Project 2025](#), and one of the ways that Republicans will [chip away at birth control access](#).

All of which is to say: These documents and websites matter. *Abortion, Every Day* will continue to collect and publish data and resources that have been removed, but it’s vital that we’re paying attention not just to what has been deleted—but why.

As difficult as it is to watch, at least we’re getting clues about what might come next.

To learn more, consider some extra credit reading:



Project 2025 & Abortion

JESSICA VALENTI · JULY 30, 2024

[Read full story →](#)



Download CDC Guidelines Removed By The Trump Admin

JESSICA VALENTI · JAN 31

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¹ *Abortion, Every Day* is saving and publishing that information [here](#).



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Bettina Longaker Bettina Longaker 4d

How the HELL is this LEGAL??? Democratic leaders, where the fuck are you????

♡ LIKE (38) 💬 REPLY

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Marsha Marsha's Substack 4d

There appears to be absolutely no power to stop this or any of the other illegal actions by the regime. Judicial if they aren't bought and paid for- too slow. Congress no power, forget the Supreme Court we can March and make calls and vote with our wallet. What else?

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20 more comments...

Presidential Documents

Executive Order 14076 of July 8, 2022

Protecting Access to Reproductive Healthcare Services

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy. Nearly 50 years ago, *Roe v. Wade*, 410 U.S. 113 (1973), articulated the United States Constitution's protection of women's fundamental right to make reproductive healthcare decisions. These deeply private decisions should not be subject to government interference. Yet today, fundamental rights—to privacy, autonomy, freedom, and equality—have been denied to millions of women across the country.

Eliminating the right recognized in *Roe* has already had and will continue to have devastating implications for women's health and public health more broadly. Access to reproductive healthcare services is now threatened for millions of Americans, and especially for those who live in States that are banning or severely restricting abortion care. Women's health clinics are being forced to close—including clinics that offer other preventive healthcare services such as contraception—leaving many communities without access to critical reproductive healthcare services. Women seeking abortion care—especially those in low-income, rural, and other underserved communities—now have to travel to jurisdictions where services remain legal notwithstanding the cost or risks.

In the face of this health crisis, the Federal Government is taking action to protect healthcare service delivery and promote access to critical reproductive healthcare services, including abortion. It remains the policy of my Administration to support women's right to choose and to protect and defend reproductive rights. Doing so is essential to justice, equality, and our health, safety, and progress as a Nation.

Sec. 2. Definitions. (a) The term “agency” means any authority of the United States that is an “agency” under 44 U.S.C. 3502(1), other than one considered to be an independent regulatory agency, as defined in 44 U.S.C. 3502(5).

(b) The term “reproductive healthcare services” means medical, surgical, counseling, or referral services relating to the human reproductive system, including services relating to pregnancy or the termination of a pregnancy.

Sec. 3. Protecting Access to Reproductive Healthcare Services. (a) Within 30 days of the date of this order, the Secretary of Health and Human Services shall submit a report to the President:

(i) identifying potential actions:

(A) to protect and expand access to abortion care, including medication abortion; and

(B) to otherwise protect and expand access to the full range of reproductive healthcare services, including actions to enhance family planning services such as access to emergency contraception;

(ii) identifying ways to increase outreach and education about access to reproductive healthcare services, including by launching a public awareness initiative to provide timely and accurate information about such access, which shall:

(A) share information about how to obtain free or reduced cost reproductive healthcare services through Health Resources and Services Administration-Funded Health Centers, Title X clinics, and other providers; and

(B) include promoting awareness of and access to the full range of contraceptive services, as well as know-your-rights information for those seeking or providing reproductive healthcare services; and

(iii) identifying steps to ensure that all patients—including pregnant women and those experiencing pregnancy loss, such as miscarriages and ectopic pregnancies—receive the full protections for emergency medical care afforded under the law, including by considering updates to current guidance on obligations specific to emergency conditions and stabilizing care under the Emergency Medical Treatment and Labor Act, 42 U.S.C. 1395dd, and providing data from the Department of Health and Human Services concerning implementation of these efforts.

(b) To promote access to reproductive healthcare services, the Attorney General and the Counsel to the President shall convene a meeting of private pro bono attorneys, bar associations, and public interest organizations in order to encourage lawyers to represent and assist patients, providers, and third parties lawfully seeking these services throughout the country.

Sec. 4. *Protecting Privacy, Safety, and Security.* (a) To address potential heightened safety and security risks related to the provision of reproductive healthcare services, the Attorney General and the Secretary of Homeland Security shall consider actions, as appropriate and consistent with applicable law, to ensure the safety of patients, providers, and third parties, and to protect the security of clinics (including mobile clinics), pharmacies, and other entities providing, dispensing, or delivering reproductive and related healthcare services.

(b) To address the potential threat to patient privacy caused by the transfer and sale of sensitive health-related data and by digital surveillance related to reproductive healthcare services, and to protect people seeking reproductive health services from fraudulent schemes or deceptive practices:

(i) The Chair of the Federal Trade Commission (FTC) is encouraged to consider actions, as appropriate and consistent with applicable law (including the Federal Trade Commission Act, 15 U.S.C. 41 *et seq.*), to protect consumers' privacy when seeking information about and provision of reproductive healthcare services.

(ii) The Secretary of Health and Human Services shall consider actions, including providing guidance under the Health Insurance Portability and Accountability Act, Public Law 104–191, 110 Stat. 1936 (1996) as amended by Public Law 111–5, 123 Stat. 115 (2009), and any other statutes as appropriate, to strengthen the protection of sensitive information related to reproductive healthcare services and bolster patient-provider confidentiality.

(iii) The Secretary of Health and Human Services shall, in consultation with the Attorney General, consider actions to educate consumers on how best to protect their health privacy and limit the collection and sharing of their sensitive health-related information.

(iv) The Secretary of Health and Human Services shall, in consultation with the Attorney General and the Chair of the FTC, consider options to address deceptive or fraudulent practices related to reproductive healthcare services, including online, and to protect access to accurate information.

Sec. 5. *Coordinating Implementation Efforts.* (a) The Secretary of Health and Human Services and the Director of the Gender Policy Council shall establish and co-chair an Interagency Task Force on Reproductive Healthcare Access (Task Force). Additional members shall include the Attorney General and the heads of other agencies as determined by the Secretary of Health and Human Services and the Director of the Gender Policy Council. The Task Force shall work to identify and coordinate activities to protect and strengthen access to essential reproductive healthcare services. In addition, the Task Force shall coordinate Federal interagency policymaking, program development, and outreach efforts to address barriers that individuals and entities may face in seeking and providing reproductive healthcare services.

The Department of Health and Human Services shall provide funding and administrative support as may be necessary for the performance and functions of the Task Force.

(b) The Attorney General shall provide technical assistance, as appropriate and consistent with applicable law, concerning Federal constitutional protections to States seeking to afford legal protection to out-of-State patients and providers who offer legal reproductive healthcare.

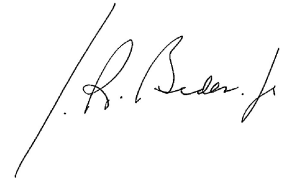
Sec. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
July 8, 2022.